UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

DEFENDANTS' PROPOSED JURY INSTRUCTIONS

Defendants submit the following proposed preliminary and concluding jury instructions for the upcoming trial in this matter. Defendants reserve the right to revise or amend these proposed instructions for any reason, including but not limited to rulings made by the Court before, during or after evidence has been received during trial, to respond to instructions proposed by Plaintiffs, or to respond to instructions proposed by the Court.

Dated: October 14, 2014

Respectfully submitted,

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PRELIMINARY INSTRUCTIONS (SECTION I)

Defendants' Proposed Preliminary Instruction No. 1: Duties of the Jury

Ladies and gentlemen: You now are the jury in this case, and I want to take a few minutes to tell you something about your duties as jurors and to give you some instructions. At the end of the trial I will give you more detailed instructions. Those instructions will control your deliberations.

It will be your duty to decide from the evidence what the facts are. You, and you alone, are the judges of the facts. You will hear the evidence, decide what the facts are, and then apply those facts to the law I give to you. That is how you will reach your verdict. In doing so you must follow that law whether you agree with it or not. The evidence will consist of the testimony of witnesses, documents and other things received into evidence as exhibits, and any facts on which the lawyers agree or which I may instruct you to accept.

You should not take anything I may say or do during the trial as indicating what I think of the believability or significance of the evidence or what your verdict should be.

First Circuit Pattern Criminal Jury Instruction 1.01.

Defendants' Proposed Preliminary Instruction No. 2: Opening Instructions

During the trial you will hear me use a few terms that you may not have heard before. Let me briefly explain some of the most common to you. The parties who sue are called the Plaintiffs. In this action, the Plaintiffs consist of two classes of purchasers of branded Nexium, along with several Opt-Out Plaintiffs which are companies that have chosen to opt out of a class and pursue their claims independent of any class. I will identify the Plaintiffs in more detail shortly. The parties being sued are called the Defendants. In this action, the defendants consist of manufacturers of branded and generic pharmaceutical products, and their corporate parents, subsidiaries, and/or affiliates. I will also identify the Defendants in more detail shortly.

You will sometimes hear me refer to "counsel." "Counsel" is another way of saying "lawyer" or "attorney." I will sometimes refer to myself as the "Court."

When I "sustain" an objection, I am excluding that evidence from this trial for a good reason. When you hear that I have "overruled" an objection, I am permitting that evidence to be admitted.

When I say "admitted into evidence" or "received in to evidence," I mean that this particular statement or the particular exhibit may be considered by you in making the decisions you must make at the end of the case.

By your verdict, you will decide disputed issues of fact. I will decide all questions of law that arise during the trial. Before you begin your deliberation at the close of the case, I will instruct you in more detail on the law that you must follow and apply.

Because you will be asked to decide the facts of this case, you should give careful attention to the testimony and evidence presented. Keep in mind that I will instruct you at the end of the trial about determining the credibility or "believability" of the witnesses. During the trial you should keep an open mind and should not form or express any opinion about the case until you have heard all of the testimony and evidence, the lawyers' closing arguments, and my instructions to you on the law.

While the trial is in progress, you must not discuss the case in any manner among yourselves or with anyone else. In addition, you should not permit anyone to discuss the case in your presence. You should avoid reading any news articles that might be published about the case.

From time-to-time during the trial, I may make rulings on objections or motions made by the lawyers. It is a lawyer's duty to object when the other side offers testimony or other evidence the lawyer believes is not admissible. You should not be biased or partial against a lawyer or the lawyer's client because the lawyer has made objections. If I sustain or uphold an objection to a question that goes unanswered by the witness, you should not draw any inferences or conclusions from the question. You should not infer or conclude from any ruling or other

comment I may make that I have any opinions on the merits of the case favoring one side or the other. I do not favor one side or the other.

The lawyers are not allowed to speak with you during this case. When you see the lawyers at a recess or pass them in the halls and they do not speak to you, they are not being rude or unfriendly; they are simply following the law.

During the trial, it may be necessary for me to talk with the lawyers out of your hearing about questions of law or procedure. Sometimes, you may be excused from the courtroom during these discussions. I will try to limit these interruptions as much as possible, but you should remember the importance of the matter you are here to determine and should be patient even though the case may seem to go slowly.

Adapted from 3 Fed. Jury Prac. & Instr. § 101:01 (6th ed.).

Defendants' Proposed Preliminary Instruction No. 3: Identification of the Parties

The Plaintiffs consist of two classes of purchasers of branded Nexium, along with several Opt-Out Plaintiffs which are companies that have chosen to opt out of a class and pursue their claims independent of any class.

The first plaintiff class, the Direct Purchaser Class, is suing on behalf of persons or entities in the United States who purchased branded Nexium directly from any of the Defendants at any time beginning April 14, 2008. The representatives of this class are American Sales Company, Meijer, Inc. and Meijer Distribution, Inc., Rochester Drug Co-Operative, Inc., Value Drug Company, and Burlington Drug Company, Inc. When I have referred to the "Direct Purchaser Class" or the "Direct Class" I have been referring to both the named Plaintiffs and the other class members in this class.

The second plaintiff class, the End Payor Class, is suing on behalf of consumers and third-party payors in certain States and the District of Columbia and Puerto Rico who purchased, paid for, and/or reimbursed some or all of the purchase price for branded Nexium products, other than for resale, beginning April 14, 2008. The representatives of this class are United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund, Allied Services Division Welfare Fund, Fraternal Order of Police Miami Lodge 20 Insurance Trust Fund, New York Hotel Trades Council & Hotel Assoc. of New York City, Inc. Health Benefits Fund, Laborers International Union of North America Local 35 Health Care Fund, International Brotherhood of Electrical Workers Local 595 Health and Welfare Fund, Laborers International Union of North America Local 17 Health Care Fund, International Union of Machinists and Aerospace Workers District No. 15 Health Fund, Michigan Regional Council of Carpenters Employee Benefits Fund, and A.F. of L. — A.G.C. Building Trades Welfare Plan. When I have referred to the "End Payor Class" or the "End Payors," I have been referring to both the named Plaintiffs and the other class members in this class.

The Court appointed these class representatives to present the cases brought on behalf of each of the classes. So although you did not hear from each individual class member, you did hear the claims of individual class representatives, and any judgment — win or lose — will be binding on the rest of the class members.

The Opt-Out Plaintiffs are companies that would have been part of the Direct Purchaser Class but chose to opt out of the Direct Purchaser Class and pursue their claims separately from that class. The Opt-Out Plaintiffs are Walgreen Co., The Kroger Co., Safeway Inc., Supervalu Inc., HEB Grocery Company LP, Rite Aid Corporation, Rite Aid Hdqtrs. Corp., JCG (PJC) USA, LLC, Maxi Drug, Inc d/b/a Brooks Pharmacy, and Eckerd Corporation.

When I refer to "Plaintiffs" generally in these instructions, I will be referring to all of the plaintiffs in this case. In other words, when I refer to "Plaintiffs" generally I will be referring to both the named class plaintiffs for each of the classes, all other class members for each of the classes, and each of the individual Opt-Out Plaintiffs.

The Defendants in this case consist of manufacturers of branded and generic pharmaceutical products, and their corporate parents, subsidiaries, and/or affiliates.

The AstraZeneca Defendants are the following entities: AstraZeneca AB, Aktiebolaget Hässle, and AstraZeneca LP. I have and will refer to these entities collectively as "AstraZeneca" unless a specific distinction needs to be made. AstraZeneca makes, among other things, branded Nexium products.

The Ranbaxy Defendants are the following entities: Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories Limited, and Ranbaxy, Inc. I have and will refer to these entities collectively as "Ranbaxy" unless a specific distinction needs to be made. Ranbaxy makes, among other things, certain generic pharmaceutical products.

The Teva Defendants are the following entities: Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. I have and will refer to these entities collectively as "Teva" unless a specific distinction needs to be made. Teva makes, among other things, certain generic pharmaceutical products.

The Dr. Reddy's or DRL Defendants are the following entities: Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. I have and will refer to these entities collectively as "Dr. Reddy's" or "DRL" unless a specific distinction needs to be made. Dr. Reddy's makes, among other things, certain generic pharmaceutical products.

Adapted from Jury Instructions in *In re TFT-LCD (Flat Panel) Antitrust Litigation*, MDL Docket No. 6036, No. 07-1827 SI (N.D. Cal.) at 3.

Defendants' Proposed Preliminary Instruction No. 4: All Persons Equal Before the Law — Corporations

You should consider and decide this case as a dispute between persons of equal standing in the community, of equal worth, and holding the same or similar stations in life. A corporation is entitled to the same fair trial as a private individual. All persons, including corporations and other organizations stand equal before the law, and are to be treated as equals.

Therefore, in examining the issues in this case, it does not matter that some of the parties are corporations or that some corporations are larger or smaller than others. You should consider and decide this case as a dispute between those of equal standing. Each party is entitled to the same fair consideration of the evidence and a decision from you based on the law as I explain it to you.

3 Fed. Jury Prac. & Instr. § 103:12 (6th ed.), and adapted from Jury Instructions in *In re TFT-LCD (Flat Panel) Antitrust Litigation*, MDL Docket No. 6036, No. 07-1827 SI (N.D. Cal.) at 3.

Defendants' Proposed Preliminary Instruction No. 5: Multiple Plaintiffs and Defendants

Although there is more than one defendant in this action, it does not follow from that fact alone that if one Defendant is liable to any plaintiff, all Defendants are liable. Each Defendant is entitled to a fair consideration of the evidence. No Defendant is to be prejudiced should you find against any other Defendant. Unless otherwise stated, all instructions I give you govern the case as to each Defendant.

There may be some evidence that could properly be considered in support of the claims of one of the defendants but not as to the claims against the other defendants. When such evidence is introduced against one, but not all, of the defendants, I will instruct you that you may consider it only with respect to the defendant or defendants as to whom it is admissible, but not as to the others.

Adapted from 3 Fed. Jury Prac. & Instr. § 103:13-14 (6th ed.).

Defendants' Proposed Preliminary Instruction No. 6: Description of Case; Summary of Applicable Law

In this case, Plaintiffs claim that Defendants violated federal and state antitrust laws. Defendants deny those claims. I will give you detailed instructions on the law at the end of the case, and those instructions will control your deliberations and decision. But in order to help you follow the evidence, I will now give you a brief summary of the elements that Plaintiffs must prove to make their case.

Plaintiffs allege that Defendants AstraZeneca and Teva violated the antitrust laws by entering into a settlement agreement to resolve patent litigation regarding the prescription drug Nexium. Plaintiffs allege that the patent litigation settlement agreement between AstraZeneca and Teva contained a "large and unexplained" payment from AstraZeneca to Teva that unlawfully delayed Teva's sale of generic Nexium beyond the date that Teva's sale of generic Nexium otherwise would have occurred in the absence of the patent litigation settlement between AstraZeneca and Teva. Plaintiffs claim that the settlement agreement between AstraZeneca and Teva amounts to (1) an unlawful agreement in restraint of trade, (2) unlawful monopolization, (3) unlawful attempted monopolization; and (4) an unlawful conspiracy to monopolize trade.

Plaintiffs also bring separate claims against Defendants Ranbaxy and Dr. Reddy's. Plaintiffs contend that Ranbaxy and Dr. Reddy's conspired with the other Defendants to delay the entry of Teva's generic Nexium product to the market. Although Ranbaxy and Dr. Reddy's had their own lawsuits against AstraZeneca over AstraZeneca's Nexium patents, and settled those cases, I instruct you that there is no evidence that the separate settlements with Ranbaxy and Dr. Reddy's caused any harm to competition on their own and therefore those agreements cannot by themselves have violated the law.

Under the circumstances alleged in this case — that is, where the allegations concern a patent litigation settlement agreement — liability for any of the alleged claims may be found only where Plaintiffs prove that the patent holder, here, AstraZeneca, made a "large and unexplained" payment to a patent challenger, here Teva, to delay generic competition. The phrase "large and unexplained payment" has a specific meaning in the antitrust law. Not every benefit that a generic company might receive in connection with a settlement agreement is a "payment," and not every payment that a generic company might receive constitutes a "large and unexplained payment" under the law.

An "unexplained" payment is one that does not reflect "traditional settlement considerations," such as (but not limited to) "avoided litigation costs," "fair value for services," and/or a reasonable compromise of a litigation claim for damages. In other words, if a payment is justified by one or more of these traditional settlement considerations, then the payment is not "unexplained."

Whether a payment is "large" depends on the specific circumstances of this case, and may be judged in comparison to, among other things, the size of the relevant market and/or the revenues that have been earned in that market by the parties to the settlement. If payment is partially explained by one or more traditional settlement considerations, you should deduct the

value of those considerations from the payment before you determine whether the remaining "unexplained" portion of any payment is "large."

In order to prove a violation of the antitrust laws on the basis of any of Plaintiffs' claims that follow, Plaintiffs must prove by a preponderance of the evidence that AstraZeneca made a "payment" to Teva, and if so, that the payment to Teva payment was both "large" and "unexplained."

If the Plaintiffs do prove that AstraZeneca made a large and unexplained payment to Teva, that alone is not enough to find an antitrust violation. Settlements with such payments do not necessarily violate the antitrust laws. In addition, Plaintiffs must prove each of the following elements by a preponderance of the evidence:

First, the existence of a contract, combination or conspiracy between or among Defendants AstraZeneca and Teva;

Second, that the contract, combination or conspiracy unreasonably restrained trade in a valid relevant antitrust market. Here, the parties have a dispute about what the relevant market is. Plaintiffs contend the relevant market consists only of brand Nexium and generic Nexium. Defendants contend that the relevant market is broader, and must include all other heartburn medication that consumers find to be good substitutes for Nexium, which at the least includes all heartburn medications in a class of drugs called "proton pump inhibitors" or PPIs; and

Third, that the restraint of trade caused Teva to delay the lawful launch of an FDA final approved generic Nexium product to a date later than it would have launched in the absence of the restraint. The parties dispute whether Teva could have lawfully launched generic Nexium before May 27, 2014 even in the absence of any agreement. Unless the agreement caused the delayed launch, there is no antitrust violation.

If you find that AstraZeneca and Teva entered into an unlawful agreement in restraint of trade, you must then decide whether or not Defendants Ranbaxy and Dr. Reddy's joined in an overarching conspiracy to restrain trade by entering into their own separate patent litigation settlement agreements with AstraZeneca. To find that either Ranbaxy or DRL joined the conspiracy, plaintiffs must prove that one or both made an agreement with Teva to delay the entry of generic Nexium into the market.

If you find that the settlement agreement between AstraZeneca and Teva was not unlawful, then you need not consider whether the settlement agreements involving Ranbaxy and Dr. Reddy's constitute conduct that demonstrates that they knowingly and intentionally joined the alleged AstraZeneca-Teva conspiracy.

In order to prove monopolization, Plaintiffs must prove each of the following elements by a preponderance of the evidence:

First, that the alleged relevant market is a valid antitrust relevant market;

Second, that AstraZeneca possessed monopoly power in that market;

Third, that AstraZeneca "willfully" acquired or maintained monopoly power in that market by engaging in anticompetitive conduct that had no rational business purpose other than to reduce competition; and

Fourth, that but for AstraZeneca's anticompetitive conduct, Teva would have lawfully launched a final FDA approved generic Nexium product prior to May 27, 2014.

Plaintiffs also allege that AstraZeneca unlawfully attempted to monopolize a relevant antitrust market. Plaintiffs must prove each of the following elements by a preponderance of the evidence:

First, that AstraZeneca engaged in anticompetitive conduct;

Second, that AstraZeneca had a specific intent to monopolize a valid relevant antitrust market;

Third, that there was a dangerous probability that AstraZeneca would achieve its goal of monopoly power in the relevant market; and

Fourth, that but for AstraZeneca's anticompetitive conduct, Teva would have lawfully launched a final FDA approved generic Nexium product prior to May 27, 2014.

Finally, Plaintiffs allege a conspiracy to monopolize trade in a valid relevant antitrust market.

With respect to the claim of conspiracy to monopolize, Plaintiffs must prove by a preponderance of the evidence each of the following elements:

First, that an agreement or mutual understanding between AstraZeneca and Teva to maintain AstraZeneca's monopoly power in a valid relevant antitrust market existed;

Second, that AstraZeneca and Teva each knowingly—that is voluntarily and intentionally—became a party to that agreement or mutual understanding;

Third, that AstraZeneca and Teva each specifically intended that the agreement would maintain AstraZeneca's monopoly power in a valid relevant antitrust market;

Fourth, that AstraZeneca and Teva each committed an overt act in furtherance of the conspiracy; and

Fifth, that, but for the alleged conspiracy to monopolize, Teva would have lawfully launched a final FDA approved generic Nexium product prior to May 27, 2014.

You should understand, however, that what I have just given you is only a preliminary outline. At the end of the trial I will give you a final instruction on these matters. If there is any difference between what I just told you, and what I tell you in the instruction I give you at the end of the trial, the instructions given at the end of the trial govern.

Third Circuit Model Civil Jury Instructions, Instruction 1.2 (modified to fit this case); First Circuit Pattern Criminal Jury Instruction 1.04 (last paragraph); *Model Jury Instructions in Civil Antitrust Cases*, ABA Section of Antitrust Law (2005 ed.), Sherman Act Section 2, Monopolization, Instruction 1; Sherman Act Section 2, Attempt to Monopolize, Instruction 1; Sherman Act-General, Instruction 2; Sherman Act-Section 2, Conspiracy to Monopolize, Instruction 1 (modified to address bifurcation issues and the allegations made in this case; interstate commerce is not a disputed issue).

Defendants' Proposed Preliminary Instruction No. 7: Burden of Proof

Plaintiffs have the burden in a civil action, such as this, to prove every essential element of Plaintiffs' claims by a preponderance of the evidence. If any Plaintiff should fail to establish any essential element of Plaintiff's claim by a preponderance of the evidence, you should find for the Defendant as to that claim.

"A preponderance of the evidence" means evidence, which as a whole, shows that the fact sought to be proved is more probable than not. In other words, a preponderance of the evidence means such evidence as, when considered and compared with the evidence opposed to it, has more convincing force, and produces in your mind a belief that what is sought to be proved is more likely true than not true. This standard does not require proof to an absolute certainty.

In determining whether any fact in issue has been proved by a preponderance of the evidence, unless otherwise instructed you may consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

Kevin O'Malley, Jay E. Grenig & William C. Lee, *Federal Jury Practice and Instructions*, § 104:01 (6th ed. 2011) (second paragraph modified).

Defendants' Proposed Preliminary Instruction No. 8: Conduct of the Jury

To ensure fairness, you as jurors must obey the following rules:

First, do not talk among yourselves about this case, or about anyone involved with it, until the end of the case when you go to the jury room to decide on your verdict;

Second, do not talk with anyone else about this case, or about anyone who has anything to do with it, until the trial has ended and you have been discharged as jurors. "Anyone else" includes members of your family and your friends. You may tell them that you are a juror, but do not tell them anything about the case until after you have been discharged by me;

Third, do not let anyone talk to you about the case or about anyone who has anything to do with it. If someone should try to talk to you, please report it to me immediately;

Fourth, during the trial do not talk with or speak to any of the parties, lawyers or witnesses involved in this case—you should not even pass the time of day with any of them. It is important not only that you do justice in this case, but that you also give the appearance of doing justice. If a person from one side of the lawsuit sees you talking to a person from the other side—even if it is simply to pass the time of day—an unwarranted and unnecessary suspicion about your fairness might be aroused. If any lawyer, party or witness does not speak to you when you pass in the hall, ride the elevator or the like, it is because they are not supposed to talk or visit with you;

Fifth, do not read any news stories or articles about the case or about anyone involved with it, or listen to any radio or television reports about the case or about anyone involved with it;

Sixth, do not do any research, such as consulting dictionaries or other reference materials, and do not make any investigation about the case on your own. You may not use any electronic devices or media, such as cell phones, smart phones (like Blackberries or iPhones), or computers of any kind; the internet, any internet device, or any text or instant messaging service (like Twitter); or any internet chat room, blog, website, or social networking service (such as Facebook, MySpace, LinkedIn, or YouTube) to communicate to anyone any information about this case or to conduct any research about this case;

Seventh, if you need to communicate with me, simply give a signed note to the [ ] to give to me; and

Eighth, do not make up your mind about what the verdict should be until after you have gone to the jury room to decide the case and you and your fellow jurors have discussed the evidence. Keep an open mind until then.

First Circuit Pattern Criminal Jury Instruction 1.07; Third Circuit Model Civil Jury Instructions, Instruction 3.1 (bracketed text under "Sixth").

Defendants' Proposed Preliminary Instruction No. 9: Outline of the Trial

The first step in the trial will be the opening statements. Attorneys for Plaintiffs will make an opening statement to you. Next, attorneys for Defendants may make an opening statement. What is said in the opening statements is not evidence. The purpose of an opening statement is only to help you understand what each party expects the evidence to show.

Then each party is given an opportunity to present its evidence.

Plaintiffs go first because Plaintiffs have the burden of proof. Plaintiffs will present witnesses whom counsel for Defendants may cross-examine, and Plaintiffs may also present evidence. Following Plaintiffs' case, Defendants may present evidence. Counsel for Plaintiffs may cross-examine witnesses for the defense. After the parties' main case is presented, they may be permitted to present what is called rebuttal evidence.

After you have heard all the evidence on both sides, the Plaintiffs and the Defendants will each be given time for their final arguments. I just told you that the opening statements by the lawyers are not evidence. The same applies to the closing arguments. They are not evidence either. In their closing arguments the lawyers for the Plaintiffs and Defendants will attempt to summarize and help you understand the evidence that was presented.

The final part of the trial occurs when I instruct you about the rules of law that you are to use in reaching your verdict. After hearing my instructions, you will leave the courtroom together to make your decisions. Your deliberations will be secret. You will never have to explain your verdict to anyone.

Third Circuit Model Civil Jury Instructions, Instruction 1.12 (modified); First Circuit Pattern Criminal Jury Instruction 1.08 (modified for civil case).

Defendants' Proposed Preliminary Instruction No. 10: Evidence; Objections; Rulings; Bench Conferences

I have mentioned the word "evidence." Evidence includes the testimony of witnesses, documents and other things received as exhibits, and any facts that have been stipulated—that is, formally agreed to by the parties.

There are rules of evidence that control what can be received into evidence. When a lawyer asks a question or offers an exhibit into evidence, and a lawyer on the other side thinks that it is not permitted by the rules of evidence, that lawyer may object. This simply means that the lawyer is requesting that I make a decision on a particular rule of evidence.

Then it may be necessary for me to talk with the lawyers out of the hearing of the jury, either by having a bench conference here while the jury is present in the courtroom, or by calling a recess. Please understand that while you are waiting, we are working. The purpose of these conferences is to decide how certain evidence is to be treated under the rules of evidence, and to avoid confusion and error. We will, of course, do what we can to keep the number and length of these conferences to a minimum.

Certain things are not evidence. I will list those things for you now:

(1) Statements, arguments, questions and comments by lawyers representing the parties in the case are not evidence.

(2) Objections are not evidence. Lawyers have a duty to their client to object when they believe something is improper under the rules of evidence. You should not be influenced by the objection. If I sustain an objection, you must ignore the question or exhibit and must not try to guess what the answer might have been or the exhibit might have contained. If I overrule the objection, the evidence will be admitted, but do not give it special attention because of the objection.

(3) Testimony that I strike from the record, or tell you to disregard, is not evidence and must not be considered.

(4) Anything you see or hear about this case outside the courtroom is not evidence, unless I specifically tell you otherwise during the trial.

Furthermore, a particular item of evidence is sometimes received for a limited purpose only. That is, it can be used by you only for a particular purpose, and not for any other purpose. I will tell you when that occurs and instruct you on the purposes for which the item can and cannot be used.

Finally, some of you may have heard the terms "direct evidence" and "circumstantial evidence." Direct evidence is testimony by a witness about what that witness personally saw or heard or did. Circumstantial evidence is indirect evidence, that is, it is proof of one or more facts from which one can find or infer another fact. You may consider both direct and circumstantial

evidence. The law permits you to give equal weight to both, but it is for you to decide how much weight to give to any evidence.

First Circuit Pattern Criminal Jury Instruction 1.05.

Defendants' Proposed Preliminary Instruction No. 11: Attorney-Client Privilege

During the trial, you may hear witnesses decline to answer questions because of the attorney-client privilege. The attorney-client privilege is a privilege recognized in federal law to encourage full and frank communications between clients and lawyers. You should know that it's perfectly proper for any witness to invoke the attorney-client privilege while testifying, and you shouldn't draw any conclusion adverse to either party simply because a witness has invoked the privilege. Nor should you speculate on what the witness might have testified if the privilege had not been raised. Confine your deliberations to the testimony that you have heard and to the documents in evidence.

Fed. R. Evid. 501; *Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981); *In re: Tudor Assocs.*, 20 F.3d 115, 120 (4th. Cir. 1994); *Astra Pharm. Prods., Inc. v. Beckman Instruments, Inc.*, 220 U.S.P.Q. 609, 612 (D. Mass. 1983), *available at* 1983 WL 51933, at *4, *aff'd*, 718 F.2d 1201 (1st Cir. 1983).

Defendants' Proposed Preliminary Instruction No. 12: Credibility of Witnesses

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You may believe everything a witness says or only part of it or none of it.

In deciding what to believe, you may consider a number of factors, including the following: (1) the witness's ability to see or hear or know the things the witness testifies to; (2) the quality of the witness's memory; (3) the witness's manner while testifying; (4) whether the witness has an interest in the outcome of the case or any motive, bias or prejudice; (5) whether the witness is contradicted by anything the witness said or wrote before trial or by other evidence; and (6) how reasonable the witness's testimony is when considered in the light of other evidence which you believe.

First Circuit Pattern Criminal Jury Instruction 1.06.

Defendants' Proposed Preliminary Instruction No. 13: Notetaking

I am going to permit you to take notes in this case, and the courtroom deputy has distributed pencils and pads for your use. I want to give you a couple of warnings about taking notes, however. First of all, do not allow your note-taking to distract you from listening carefully to the testimony that is being presented. If you would prefer not to take notes at all but simply to listen, please feel free to do so. Please remember also from some of your grade-school experiences that not everything you write down is necessarily what was said. Thus, when you return to the jury room to discuss the case, do not assume simply because something appears in somebody's notes that it necessarily took place in court. Instead, it is your collective memory that must control as you deliberate upon the verdict. Please take your notes to the jury room at every recess. I will have the courtroom deputy collect them at the end of each day and place them in the vault. They will then be returned to you the next morning. When the case is over, your notes will be destroyed. These steps are in line with my earlier instruction to you that it is important that you not discuss the case with anyone or permit anyone to discuss it with you.

First Circuit Pattern Criminal Jury Instruction 1.08.

Defendants' Proposed Preliminary Instruction No. 14: Jury Questions for Witnesses

You will have the opportunity to ask questions of the witnesses in writing. When a witness has been examined and cross-examined by counsel, and after I ask any clarifying questions of the witness, I will ask whether any juror has any further clarifying questions for the witness.

If so, you will write your questions on a piece of paper, and hand it to my Deputy Clerk. Do not discuss your question with any other juror. I will review your question with counsel at sidebar and determine whether the question is appropriate under the rules of evidence. If so, I will ask your question, though I might put it in my own words. If the question is not permitted by the rules of evidence, it will not be asked, and you should not draw any conclusions about the fact that your question was not asked. Following your questions, if any, the attorneys may ask additional questions. If I do ask your question you should not give the answer to it any greater weight than you would give to any other testimony.

Third Circuit Model Civil Jury Instructions, Instruction 1.8.

CONCLUDING INSTRUCTIONS (SECTION II)

Defendants' Proposed Final Instruction No. 1: Duty of the Jury to Find Facts and Follow Law

It is your duty to find the facts from all the evidence admitted in this case. To those facts you must apply the law as I give it to you. The determination of the law is my duty as the presiding judge in this court. It is your duty to apply the law exactly as I give it to you, whether you agree with it or not. You must not be influenced by any personal likes or dislikes, prejudices or sympathy. That means that you must decide the case solely on the evidence before you and according to the law. You will recall that you took an oath promising to do so at the beginning of the case.

In following my instructions, you must follow all of them and not single out some and ignore others; they are all equally important. You must not read into these instructions, or into anything I may have said or done, any suggestions by me as to what verdict you should return—that is a matter entirely for you to decide.

First Circuit Pattern Criminal Jury Instruction 3.01.

Defendants' Proposed Final Instruction No. 2: What Is Evidence; Inferences

The evidence from which you are to decide what the facts are consists of sworn testimony of witnesses, both on direct and cross-examination, regardless of who called the witness; the exhibits that have been received into evidence; and any facts to which the lawyers have agreed or stipulated. A stipulation means simply that the plaintiffs and defendants accept the truth of a particular proposition or fact. Since there is no disagreement, there is no need for evidence apart from the stipulation. You must accept the stipulation as fact to be given whatever weight you choose.

Although you may consider only the evidence presented in the case, you are not limited in considering that evidence to the bald statements made by the witnesses or contained in the documents. In other words, you are not limited solely to what you see and hear as the witnesses testify. You are permitted to draw from facts that you find to have been proven such reasonable inferences as you believe are justified in the light of common sense and personal experience.

First Circuit Pattern Criminal Jury Instruction 3.04.

Defendants' Proposed Final Instruction No. 3: Kinds of Evidence: Direct and Circumstantial

There are two kinds of evidence: direct and circumstantial. Direct evidence is direct proof of a fact, such as testimony of an eyewitness that the witness saw something. Circumstantial evidence is indirect evidence that is proof of a fact or facts from which you could draw the inference, by reason and common sense, that another fact exists, even though it has not been proven directly. You are entitled to consider both kinds of evidence. The law permits you to give equal weight to both, but it is for you to decide how much weight to give to any evidence.

There is a special rule in antitrust cases for inferring the existence of a conspiracy from circumstantial evidence. The antitrust laws prohibit only agreements to limit competition; they do not prohibit companies from making independent decisions to act in the same way, even if the effect of those actions is the same. The law does not permit you to infer from the Defendants' simply acting in the same way that there is a conspiracy.

For example, it is illegal for two gas station owners who share the same street to reach an agreement to fix the price of gas. It is perfectly legal, however, for each owner to look at the price on the other's sign and set her price accordingly. If there were a case alleging that the two owners had agreed to fix prices, and the only evidence was that their prices were the same, you could not infer from that evidence the existence of a conspiracy. Instead, the evidence must tend to exclude the possibility that the Defendants' acted independently. I will instruct you on this issue in more detail shortly.

First Circuit Pattern Criminal Jury Instruction 3.05; *White v. R.M. Packer*, 635 F.3d 571, 575 (1st Cir. 2011).

Defendants' Proposed Final Instruction No. 4: Credibility of Witnesses

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You may believe everything a witness says or only part of it or none of it.

In deciding what to believe, you may consider a number of factors, including the following: (1) the witness's ability to see or hear or know the things the witness testifies to; (2) the quality of the witness's memory; (3) the witness's manner while testifying; (4) whether the witness has an interest in the outcome of the case or any motive, bias or prejudice; (5) whether the witness is contradicted by anything the witness said or wrote before trial or by other evidence; and (6) how reasonable the witness's testimony is when considered in the light of other evidence which you believe.

First Circuit Pattern Criminal Jury Instruction 3.06.

Defendants' Proposed Final Instruction No. 5: Use of Depositions as Evidence

During the trial, certain testimony has been presented by way of deposition. The deposition consisted of sworn, recorded answers to questions asked of the witness in advance of the trial by attorneys for the parties to the case. The testimony of a witness who, for some reason, is not present to testify from the witness stand may be presented in writing under oath or on a videotape. Such testimony is entitled to the same consideration and is to be judged as to credibility, and weighed, and otherwise considered by you, insofar as possible, in the same way as if the witness had been present and had testified from the witness stand.

Kevin O'Malley, Jay E. Grenig & William C. Lee, *Federal Jury Practice and Instructions*, § 105:02 (6th ed. 2011).

Defendants' Proposed Final Instruction No. 6: Weighing the Testimony of an Expert Witness

You have heard testimony from persons described as experts. An expert witness has special knowledge or experience that allows the witness to give an opinion.

You may accept or reject such testimony. In weighing the testimony, you should consider the factors that generally bear upon the credibility of a witness as well as the expert witness's education and experience, the soundness of the reasons given for the opinion and all other evidence in the case.

In this trial, these witnesses were, at times, asked hypothetical questions and they gave answers to such questions. In answering a hypothetical question, an expert witness must accept as true every asserted fact stated therein, but this does not mean that you must. If you find that assumed facts are not proven, you should disregard the answer based on the hypothetical question.

When a witness is being paid for reviewing and testifying concerning the evidence, you may consider the possibility of bias and should view with caution the testimony of such witness where court testimony is given with regularity and represents a significant portion of the witness's income.

Remember that you alone decide how much of a witness's testimony to believe, and how much weight it should be given. If you should decide the opinion of an expert witness is not based upon sufficient education and experience, or if you should conclude the reasons given in support of the opinion are not sound, or if you feel the expert's opinion is outweighed by other evidence, you may disregard the opinion entirely.

First Circuit Pattern Criminal Jury Instruction 2.07; Expert Witness Instruction, Judge Hornby (D. Maine) (third paragraph herein); Third Circuit Model Civil Jury Instructions, Instruction 2.11 (fourth paragraph herein); Eleventh Circuit Civil Pattern Jury Instructions, Instruction 3.6.2 (fourth paragraph herein (second option)); Kevin O'Malley, Jay E. Grenig & William C. Lee, *Federal Jury Practice and Instructions*, § 104:40 (6th ed. 2011) (last sentence herein).

Defendants' Proposed Final Instruction No. 7: Cautionary and Limiting Instructions as to Particular Kinds of Evidence

A particular item of evidence is sometimes received for a limited purpose only. That is, it can be used by you only for one particular purpose, and not for any other purpose. For example, a statement made by one defendant may be admitted in support of a claim against that defendant, but not in support of a claim against the other defendants, who did not make or authorize the statement. I have told you when that occurred, and instructed you on the purposes for which the item can and cannot be used.

First Circuit Pattern Criminal Jury Instruction 3.07.

Defendants' Proposed Final Instruction No. 8: What Is Not Evidence

Certain things are not evidence. I will list them for you:

(1) Arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they say in their opening statements, closing arguments and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them from the evidence differ from the way the lawyers have stated them, your memory of them controls.

(2) Questions and objections by lawyers are not evidence. Lawyers have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objection or by my ruling on it.

(3) Anything that I have excluded from evidence or ordered stricken and instructed you to disregard is not evidence. You must not consider such items.

(4) Anything you may have seen or heard when the court was not in session is not evidence. You are to decide the case solely on the evidence received at trial.

(5) The complaint is not evidence. It is the means by which the Plaintiffs' claims are brought before this court. It proves nothing.

First Circuit Pattern Criminal Jury Instruction 3.08 (modified to refer to complaint rather than indictment).

Defendants' Proposed Final Instruction No. 9: Charts and Summaries Not Received in Evidence

Certain charts and summaries not received in evidence have been shown to you in order to help explain the contents of books, records, documents, or other evidence in the case. They are not themselves evidence or proof of any facts. If they do not correctly reflect the facts or figures shown by the evidence in the case, you should disregard these charts and summaries and determine the facts from the underlying evidence.

Ninth Circuit Model Civil Jury Instruction 2.12.

Defendants' Proposed Final Instruction No. 10: Use of Notes Taken by a Juror

Any notes that you have taken during this trial are only aids to your memory. If your memory differs from your notes, you should rely on your memory and not on the notes. The notes are not evidence. If you have not taken notes, you should rely on your independent recollection of the evidence and should not be unduly influenced by the notes of other jurors. Notes are not entitled to any greater weight than the recollection or impression of each juror about the testimony.

Fifth Circuit Pattern Jury Instructions—Civil, Instruction No. 2.20.

Defendants' Proposed Final Instruction No. 11: No Inference from Judge's Questions

During this trial, I have asked a witness a question myself. Do not assume that because I asked questions I hold any opinion on the matters I asked about, or on what the outcome of the case should be.

Seventh Circuit Model Jury Instructions (Civil), Instruction 1.02.

Defendants' Proposed Final Instruction No. 12: Attorney-Client Privilege

During the trial, you heard witnesses decline to answer questions because of the attorney-client privilege. The attorney-client privilege is a privilege recognized in federal law to encourage full and frank communications between clients and lawyers. You should know that it's perfectly proper for any witness to invoke the attorney-client privilege while testifying, and you shouldn't draw any conclusion adverse to either party simply because a witness has invoked the privilege. Nor should you speculate on what the witness might have testified if the privilege had not been raised. Confine your deliberations to the testimony that you have heard and to the documents in evidence.

Fed. R. Evid. 501; *Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981); *In re: Tudor Assocs.*, 20 F.3d 115, 120 (4th. Cir. 1994); *Astra Pharm. Prods., Inc. v. Beckman Instruments, Inc.*, 220 U.S.P.Q. 609, 612 (D. Mass. 1983), *available at* 1983 WL 51933, at *4, *aff'd*, 718 F.2d 1201 (1st Cir. 1983).

Defendants' Proposed Final Instruction No. 13: Burden of Proof

Plaintiffs have the burden in a civil action, such as this, to prove every essential element of Plaintiffs' claims by a preponderance of the evidence. If Plaintiffs should fail to establish any essential element of Plaintiffs' claims by a preponderance of the evidence, you should find for Defendants as to that claim.

"A preponderance of the evidence" means evidence, which as a whole, shows that the fact sought to be proved is more probable than not. In other words, a preponderance of the evidence means such evidence as, when considered and compared with the evidence opposed to it, has more convincing force, and produces in your mind a belief that what is sought to be proved is more likely true than not true. This standard does not require proof to an absolute certainty.

In determining whether any fact in issue has been proved by a preponderance of the evidence, unless otherwise instructed you may consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

Kevin O'Malley, Jay E. Grenig & William C. Lee, *Federal Jury Practice and Instructions*, § 104:01 (6th ed. 2011) (second paragraph modified).

Defendants' Proposed Final Instruction No. 14: Presumption of Regularity

Unless outweighed by evidence to the contrary, you may find an official duty has been regularly performed, private transactions have been fair and regular, the ordinary course of business has been followed, things have happened according to the ordinary course of nature and the ordinary habits of life, and the law has been obeyed.

Kevin O'Malley, Jay E. Grenig & William C. Lee, *Federal Jury Practice and Instructions*, § 104:21 (6th ed. 2011) (referenced to "employment" omitted because inapplicable).

Defendants' Proposed Final Instruction No. 15: Multiple Claims/Multiple Plaintiffs/Defendants

You must give separate consideration to each claim and each party in this case. Although there are four defendants, it does not follow that if one is liable, all of the others is also liable.

Each Defendant is entitled to a fair consideration of the evidence. No Defendant is to be prejudiced should you find against another Defendant.

Unless I state otherwise, you should consider each instruction given to apply separately and individually to each Plaintiff and to each Defendant in the case.

In this case, I will give you instructions with respect to the AstraZeneca-Teva settlement agreement. If you find that this agreement was unlawful, you will then proceed to determine whether Ranbaxy or Dr. Reddy's (or both) joined the AstraZeneca-Teva agreement. If you find that the AstraZeneca-Teva settlement agreement was not unlawful, you do not need to consider whether Ranbaxy or Dr. Reddy's joined a conspiracy with Teva and AstraZeneca.

Seventh Circuit Model Jury Instructions (Civil), Instruction 1.25 (first paragraph herein); Kevin O'Malley, Jay E. Grenig & William C. Lee, *Federal Jury Practice and Instructions*, §§ 103:10, 103.14 (6th ed. 2011) (second and third paragraphs herein).

Defendants' Proposed Final Instruction No. 16: Evidence Limited to Certain Parties

Each party is entitled to have the case decided solely on the evidence that applies to that party. When evidence was admitted with respect to only one Defendant, it must be considered only with respect to that Defendant. You must not consider it with respect to any other Defendant.

Seventh Circuit Model Jury Instructions (Civil), Instruction 1.10 (modified).

Defendants' Proposed Final Instruction No. 17: Number of Witnesses

The weight of the evidence to prove a fact does not necessarily depend on the number of witnesses who testify. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves.

You may find the testimony of a small number of witnesses as to any fact is more credible than the testimony of a larger number of witnesses to the contrary.

Third Circuit Model Civil Jury Instructions, Instruction 3.2 (first paragraph herein); Kevin O'Malley, Jay E. Grenig & William C. Lee, *Federal Jury Practice and Instructions*, § 104:54 (6th ed. 2011) (last sentence herein) (excerpt).

Defendants' Proposed Final Instruction No. 18: Corporate Party

The fact that certain parties are corporations should not affect your decision.

The word "person" in my instructions includes not only every individual, but also every corporation, partnership, and every other organization, of any kind.

You should consider and decide this case as a dispute between persons of equal standing in the community, of equal worth, and holding the same or similar stations in life. A corporation is entitled to the same fair trial as a private individual. All persons, including corporations and other organizations, stand equal before the law, and are to be treated as equals.

Instruction, Liability of Corporations, Judge Hornby (D. Maine), *available at* http://www.med.uscourts.gov/civil (first sentence); Kevin O'Malley, Jay E. Grenig & William C. Lee, *Federal Jury Practice and Instructions*, § 103:12 (6th ed. 2011) (last paragraph).

Defendants' Proposed Final Instruction No. 19: Patents -- Generally

AstraZeneca owns a number of patents relating to Nexium. Some general information about patents is necessary to evaluate this case.

The U.S. Constitution gives Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their discoveries." To carry out this provision of the Constitution, Congress has enacted the patent laws. The basic policy of the patent laws is to encourage inventors to reveal new, useful, and unobvious technology to the public, in exchange for the grant by the U.S. government of a patent on their inventions.

To receive a patent, an inventor pays a fee and submits an application to the U.S. Patent Office. The Patent Office reviews the application and, if it finds that the application adequately describes a new and useful invention, it grants, or "issues" a patent to the inventor. The patent provides an inventor the right, for a specified number of years (usually 20 years), to exclude others from making, using, offering for sale, or selling the patented invention throughout the United States without the permission of the owner of the patent. This potential economic reward gives people an incentive to invest time, money, and effort in research and development efforts.

A patent benefits the public as well as the patent owner. This is because every inventor who applies for a patent must provide the details of his or her invention to the Patent Office. When the Patent Office issues a patent, a full description of the invention is included in a publicly filed document that precisely defines what the patent covers. This public filing allows anyone to find out what was invented and how it works. Thus, other researchers can learn from a patent owner's work, and can make other inventions of their own.

A person may obtain from the Patent Office a separate patent for each invention that qualifies for a patent. There is no maximum number of patents that a person may obtain.

After a patent expires, anyone is free make, use or sell the invention or inventions covered by it. Using a patented invention before the patent expires, without the patent owner's permission, is called patent infringement or infringing the patent. As mentioned above, for a specified number of years, the patent owner has the right to exclude anyone else from using the patented invention. He or she may enforce this right by bringing a lawsuit to stop the alleged infringement, to recover damages for the alleged infringement, or both.

The company accused of infringement may dispute the allegation, and may also assert that the patent or patents are invalid. Because patents involved in such litigation have been reviewed and issued by the Patent Office, they are presumptively valid. A company that argues in litigation that a patent is actually invalid must prove its case by clear and convincing evidence. That is a higher level of proof than the preponderance-of-evidence standard on which I have already instructed you.

Model Jury Instructions in Civil Antitrust Cases, ABA Section of Antitrust Law (2005 ed.), Patents-General, Instruction 1 (modified to fit this case).

Defendants' Proposed Final Instruction No. 20: Patents – This Case

As I told you, the agreement that the Plaintiffs challenge in this case as an antitrust violation settled patent litigation between AstraZeneca and Teva. In that litigation, AstraZeneca claimed that Teva's generic Nexium infringed various AstraZeneca patents relating to Nexium. I am going to describe those patents with some of the terminology used by some of the witnesses whose testimony you heard.

The Enantiomer Patents are U.S. Patent Nos. 5,877,192, 6,875,872, and 5,714,504. They are sometimes referred to in the evidence as the '192 patent, the '872 patent, and the '504 patent. The '192 and '872 patents expired on May 27, 2014, and the '504 patent expires on February 3, 2015.

In the New Jersey litigation, Teva admitted that it infringed the '192 patent and the '872 patent, but contended that those patents were invalid. Teva denied that it infringed any claims of the '504 patent, or if it did that this patent was invalid also.

The Trihydrate Patents are U.S. Patent Nos. 6,369,085 and 7,411,070, or the '085 patent and the '070 patent. Both of these patents expire on May 25, 2018. Teva denied that it infringed these patents, or alternatively that the patents were invalid.

The Process Patent is U.S. Patent No. 5,948,789, or the '789 patent. It expires on July 14, 2015. Teva denied that it infringed this patent, or alternatively the patent was invalid.

When referring to these different groups of patents collectively, I will use the term "Nexium Patents."

Defendants' Proposed Final Instruction No. 21: Patents – License

A patent owner may give someone else permission to use the invention before the patent expires. This is called licensing the patent, and the permission usually is formally set out in a patent license agreement. The firm or person receiving permission to use the patent is called the licensee or license holder. The settlement agreement between AstraZeneca and Teva includes a license giving Teva permission to use all of the inventions covered by the Nexium Patents, starting on May 27, 2014. Without the license, Teva could not have lawfully started selling its generic Nexium until 2018 unless Teva won the patent litigation with AstraZeneca.

Model Jury Instructions in Civil Antitrust Cases, ABA Section of Antitrust Law (2005 ed.), Patents-General, Instruction 1 (modified to fit this case).

Defendants' Proposed Final Instruction No. 22: Patents: Relation to Antitrust Laws

The patent laws complement the antitrust laws in promoting competition. The basic purpose of both sets of laws is to promote innovation, industry, and competition. In general, the antitrust laws seek to promote competition by prohibiting the abuse of monopoly power and restraints on trade that unduly interfere with the competitive process.

The patent laws seek to promote competition by encouraging people to invest in scientific research and product development. These investments can lead to new and better products, better ways of making things, new jobs, and entirely new industries. But a patent necessarily limits competition until the patent expires — by giving the patent holder the right to exclude others from using the patented invention for the duration of the patent. The patent holder's enforcement and protection of this right to exclude is not an antitrust violation.

Thus, as long as the patent owner acts only to take full advantage of the right the patent laws give him or her to stop others from copying the invention, he or she does not violate the antitrust laws. If, on the other hand, the patent owner seeks to restrain trade beyond the right to exclude conferred by the patent, his or her conduct may be an antitrust violation.

As described in more detail in the instructions that follow, it is not a violation of the antitrust laws to settle patent litigation unless, as threshold matter, the patent settlement contains a "large and unexplained" payment from the patent holder to the patent challenger that delays entry of the patent challenger's competing product, and is not otherwise justified by the procompetitive benefits of the settlement. Only if a patent litigation settlement contains a "large and unexplained" payment from the patent holder to the patent challenger may a patent settlement be further assessed under the antitrust laws for a determination of its potential unlawfulness.

Adapted from ABA Model Jury Instructions in Civil Antitrust Cases, D-8 (2005 ed.).

Defendants' Proposed Final Instruction No. 23: Hatch-Waxman Act

You have heard reference to the Hatch-Waxman Act. Some general information about the Hatch Waxman Act is necessary to evaluate this case.

Congress passed the Hatch-Waxman Act to strike a balance between two competing policy interests: (1) encouraging pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.

Before a generic drug can be lawfully sold in the United States, the Food and Drug Administration ("FDA") must approve the drug for sale. The FDA must give final approval of a drug before it can be sold lawfully in the United States. Tentative approval by the FDA is not sufficient.

A pioneering drug company seeking FDA approval of a new drug must submit a New Drug Application ("NDA") that includes extensive test data, usually from a series of clinical trials, proving the safety and efficacy of the drug. Generic competitors are permitted to submit an Abbreviated New Drug Application ("ANDA") that shortens this process. The ANDA is permitted to prove the safety and efficacy of the generic drug through evidence that it is the equivalent of the pioneering drug and therefore would have the same safety and efficacy, rather than through independent human trials or other test results.

The ANDA also must establish that the generic drug will not infringe patents governing the equivalent pioneering drug. To accomplish this, the Hatch-Waxman Act provides that a pioneering drug company's NDA must disclose all patents that cover the drug. The FDA lists all such patents in a publication commonly referred to as the "Orange Book," providing notice of the pioneering drug company's patents to the public.

If an Orange-Book-listed patent covers a drug, a generic drug manufacturer seeking approval of a generic version of the drug must file a certification asserting that the patent either is invalid or that it is not infringed by the proposed generic drug. If the Orange-Book-listed patent holder files a lawsuit alleging patent infringement by the generic applicant within 45 days after receiving notice of the certification, then the ANDA application is automatically stayed for up to 30 months. The FDA may grant tentative approval of an ANDA during this 30-month period, but it cannot grant final approval unless the lawsuit is resolved prior to that time.

To encourage a generic drug company to take on the potential burden and expense of challenging an Orange-Book-listed patent, the Hatch-Waxman Act grants the first ANDA applicant that files a certification a 180-day period of market exclusivity. The period of exclusivity prohibits the FDA from granting final approval of any other generic drug based on the same NDA until the first ANDA filer's period of exclusivity has either concluded or been forfeited.

I instruct you that Defendant Ranbaxy was the first ANDA applicant to file a certification with respect to generic Nexium. The Hatch-Waxman Act granted Ranbaxy a 180-day period of market exclusivity. The 180-day period of market exclusivity does not begin until the first

ANDA filer (Ranbaxy) begins commercial marketing of the generic drug product. In this case, the undisputed facts are that Ranbaxy could not have obtained final FDA approval before May 27, 2014, even if there had been no settlement of the Nexium patent litigation with AstraZeneca.

If, however, a different ANDA filer with tentative FDA approval obtains a final court decision that all patents listed as protecting the referenced branded drug (here, Nexium) are invalid, unenforceable, or not infringed, then the first ANDA filer must begin selling its product within 75 days of the final court decision or it will forfeit the 180-day exclusivity period. The Court has ruled that there is insufficient evidence to conclude that Teva would have successfully obtained a final court decision that all challenged patents were invalid, unenforceable or not infringed before May 27, 2014. Accordingly, you may not find that Teva would have been able to launch a generic version of Nexium before May 27, 2014 because it would have prevailed at trial in its patent litigation with AstraZeneca.

The only other way for a different ANDA filer to lawfully begin selling its product before the first ANDA filer's 180-day exclusivity period is if the first ANDA filer selectively waives or relinquishes its exclusivity period. A first ANDA filer can selectively waive and thereby effectively transfer its exclusivity period to a different ANDA filer only if the first ANDA filer gets final FDA approval and begins commercially marketing the generic drug product. Because the Court has determined that there is insufficient evidence that Ranbaxy could have obtained final FDA approval to launch a generic Nexium product prior to May 27, 2014, you may not conclude that Teva could have launched a generic Nexium product as the result of a selective waiver of its 180-day exclusivity by Ranbaxy.

Alternatively, a first ANDA filer can voluntarily relinquish its exclusivity, in which event no ANDA filer is thereafter entitled to the 180-day period of market exclusivity and any and all ANDA filers with final FDA approval may launch a generic product. I instruct you that Plaintiffs' theory that Ranbaxy would have voluntarily relinquished its 180-day period of marketing exclusivity in this manner is the only theory that you may consider when determining whether or not Teva could and would have launched a generic Nexium product prior to May 27, 2014 had there been no settlement with AstraZeneca.

Defendants' Proposed Final Instruction No. 24: Large and Unexplained Payment

Parties to litigation are permitted to enter into settlement agreements, and settlements of litigation are commonplace. Under the circumstances alleged in this case — that is, where the allegations concern a patent litigation settlement agreement — liability for any of the alleged claims that follow may be found only where Plaintiffs first prove that the patent holder, here, AstraZeneca, also made a "large and unexplained" payment to a patent challenger, here Teva, that (1) delays the entry of generic competition past the date such competition would otherwise occur, and (2) is unjustified by other precompetitive benefits of the settlement.

The phrase "large and unexplained payment" has a specific meaning in the antitrust law. Not every benefit that a generic company might receive in connection with a settlement agreement is a "payment," and not every payment that a generic company might receive constitutes a "large and unexplained payment" under the law.

An "unexplained" payment is one that does not reflect "traditional settlement considerations," such as (but not limited to) "avoided litigation costs," "fair value for services," and/or a reasonable compromise of a litigation claim for damages. In other words, if a payment is justified by one or more of these traditional settlement considerations, then the payment is not "unexplained." Here, plaintiffs claim that AstraZeneca's settlement of a different lawsuit involving the heartburn medication Prilosec was so favorable to Teva that it must have been a payment for Teva to settle the Nexium case. If you find that a reasonable party in AstraZeneca's position would have settled the Prilosec case for that amount even if the Nexium case did not exist, then the Prilosec settlement cannot be "unexplained" as that term is used here.

Whether a payment is "large" depends on the specific circumstances of a particular case, and may be judged in comparison to, among other things, the size of the relevant market and/or the revenues that have been earned in that market by the parties to the settlement. If payment is partially explained by one or more traditional settlement considerations, you should deduct the value of those considerations from the payment before you determine whether the remaining "unexplained" portion of any payment is "large."

You are required to make a determination as to whether AstraZeneca made a "payment" to Teva, and if so whether that payment was both "large" and "unexplained." If you find that Plaintiffs have failed to prove by a preponderance of the evidence that AstraZeneca made a "payment" to Teva, and/or fail to prove that any such payment was "large" or "unexplained," then you should so note this finding on the appropriate verdict form.

If you conclude that AstraZeneca made a "large and unexplained" payment to Teva, that is not sufficient to find in favor of the Plaintiffs with respect to the Teva/AstraZeneca agreement. You must then separately evaluate the remaining elements of Plaintiffs' claims. That evaluation requires consideration of multiple factors, which I will explain to you shortly.

FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227, 2237 (2013).

Defendants' Proposed Final Instruction No. 25: Large and Unexplained Payment: Compromise of Claim for Damages; Reasonable Royalty

In this case, Plaintiffs allege that AstraZeneca and Teva's patent litigation settlement contained a large and unexplained payment from AstraZeneca to Teva in the form of a second patent litigation settlement regarding the drug Prilosec. Plaintiffs allege that the $9 million that Teva paid to AstraZeneca in January 2010 to settle the Prilosec patent infringement litigation was so far below what Teva would have been required to pay had damages been assessed in litigation that it amounted to a disguised payment from AstraZeneca to Teva in order to induce Teva to agree to delay its entry date with respect to generic Nexium.[1]

In determining whether the Prilosec settlement between AstraZeneca and Teva was a disguised "large and unexplained payment" to Teva in connection with the Nexium settlement, you should consider whether the Prilosec settlement was a fair or reasonable compromise of that litigation, including but not limited to the following:

- The legal standards governing the litigation, including the determination of liability and the calculation of any damages;
- Litigation uncertainty as to the success of any claim, counterclaim or defense, including its impact as to a negotiated settlement discount regarding any estimated damages;
- The strength of the legal claims and defenses;
- The procedural posture of the litigation;
- Saved litigation expenses avoided through settlement, including through any appeal; and
- The financial value to AstraZeneca of receiving a sum certain ($9 million) at the time of the settlement in January 2010 rather than having to wait years to collect a potential litigation recovery.

In order to aid in your determination of any damages that would have been assessed in the Prilosec litigation absent the settlement, I will now briefly describe some of the claims and legal standards at issue in that case, which was pending in a federal court (just like this one) in

[1]Nothing in this proposed instruction constitutes, or should be construed as, a waiver of defendants' position that the compromise of a patent damages claim at an alleged discount cannot constitute a reverse payment as a matter of law under *Actavis*. Defendants submit this proposed instruction based solely on the Court's summary judgment ruling to the contrary, and expressly reserve their rights to challenge that ruling on appeal.

the Southern District of New York and that would have been decided by Judge Denise Cote absent the settlement.

In the Prilosec litigation, AstraZeneca sued Teva for selling generic Prilosec (omeprazole) that was manufactured by another defendant, Impax, that AstraZeneca claimed infringed its patents on the brand name prescription drug Prilosec. Teva counterclaimed and asserted that AstraZeneca's patents were invalid and unenforceable and that its omeprazole product did not infringe AstraZeneca's patents. In determining whether AstraZeneca's patents were valid and enforceable, the court in the Prilosec litigation would perform an analysis of whether Teva proved that AstraZeneca did not meet any of several important technical requirements to obtain a valid and enforceable patent from the Patent and Trademark Office. In determining whether Teva infringed those patents, the court in the Prilosec litigation would perform an analysis of whether AstraZeneca proved that Teva's omeprazole product infringed the specific claims, that is, the specific description of the patented invention, found in AstraZeneca's patents. Prior to the settlement, the court had already found that Impax had infringed AstraZeneca's Prilosec patents, but Teva was disputing that it could be bound by that ruling.

If, and only if, AstraZeneca prevailed in proving to the judge in that case that Teva infringed its valid and enforceable patents, AstraZeneca would be entitled to "reasonable royalty" damages, which amount to an estimate of the royalty rate on Teva's sales of generic omeprazole. Reasonable royalty damages seek to measure the amount in royalties that the infringer would have paid to the patent holder (AstraZeneca) had the technology been properly licensed during the period of infringement. The most commonly accepted methodology for the calculation of reasonable royalty damages is something called the *Georgia-Pacific* "hypothetical negotiation" approach – the name comes from a case involving Georgia-Pacific railroad. Under this approach, the court applies a list of fifteen factors (which I will describe for you momentarily) to determine what royalty rate would have been negotiated between a "willing licensor" and a "willing licensee" at the time the infringement began, which here is alleged to be September 2004 . The resulting royalty rate is then multiplied by the infringer's actual net sales or actual profits during the period of infringement in order to determine the total "reasonable royalty" due.

In determining the reasonable royalty rate, the court in the Prilosec litigation would perform a so-called *Georgia-Pacific* analysis. The fifteen *Georgia-Pacific* factors are as follows:

1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty;

2. The rates paid by the licensee for the use of other patents comparable to the patent in suit;

3. The nature and scope of the license, as exclusive or nonexclusive, or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold;

4. The licensor's established policy and marketing program to maintain a patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly;

5. The commercial relationship between the licensor and licensee, such as whether they are competitors in the same territory in the same line of business, or whether they are inventor and promoter;

6. The effect of selling the patented specialty in promoting sales of other products of the licensee, the existing value of the invention to the licensor as a generator of sales of non-patented items, and the extent of such derivative or convoyed sales;

7. The duration of the patent and the term of the license;

8. The established profitability of the product made under the patent, its commercial success, and its current popularity;

9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results;

10. The nature of the patented invention, the character of the commercial embodiment of it as owned and produced by the licensor, and the benefits to those who have used the invention;

11. The extent to which the infringer has made use of the invention and any evidence probative of the value of that use;

12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions;

13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer;

14. The opinion testimony of qualified experts; and

15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

As I have stated, in determining whether the Prilosec settlement between AstraZeneca and Teva was a disguised "large and unexplained payment" to Teva in connection with the Nexium settlement, you should consider whether the Prilosec settlement was a fair or reasonable compromise of that litigation based on all of the circumstances at the time of settlement, and not just the *Georgia-Pacific* legal factors that I have just described.

FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227, 2233-34 (2013); *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970), *modified and aff'd sub nom.*, *Georgia Pacific Corp. v. United States Plywood Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971); *AstraZeneca AB v. Apotex Corp.*, 985 F. Supp. 2d 452, 489 (S.D.N.Y. 2013).

Defendants' Proposed Final Instruction No. 26: Sherman Act Section 1 – General

Plaintiffs challenge the Defendants' conduct under Section 1 of the Sherman Act. Section 1 prohibits contracts, combinations and conspiracies that unreasonably restrain trade. With respect to this claim, Plaintiffs must prove the following:

First, the existence of a contract, combination or conspiracy between or among at least two separate entities;

Second, that the contract, combination or conspiracy unreasonably restrained trade in a valid relevant antitrust market; and

Third, that the restraint of trade caused Teva to delay the lawful launch of an FDA final-approved generic Nexium product to a date later than it would have in the absence of the restraint.

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-General, Instruction 2 (modified based on bifurcation of issues) (interstate commerce is not a disputed issue).

Defendants' Proposed Final Instruction No. 27: Sherman Act Section 1 – Contract, Combination or Conspiracy Between AstraZeneca and Teva

Plaintiffs allege the existence of two conspiracies to restrain trade: (1) an alleged conspiracy between AstraZeneca and Teva, and (2) an overarching conspiracy among all four defendants (AstraZeneca, Ranbaxy, Teva, and Dr. Reddy's). One of your jobs will be to determine whether such conspiracies were in fact formed, and if so, whether they were anticompetitive.

This instruction relates to Plaintiffs' allegation that AstraZeneca and Teva entered into a two-party conspiracy. Plaintiffs allege that AstraZeneca and Teva participated in a conspiracy to restrain trade by agreeing to settle the Nexium patent litigation between AstraZeneca and Teva in a manner that delayed Teva's sale of generic Nexium to a date later than Teva would have lawfully sold generic Nexium in the absence of the alleged conspiracy in exchange for a "large and unexplained payment" from AstraZeneca to Teva.

A conspiracy is an agreement by two or more persons to accomplish some unlawful purpose or to accomplish a lawful purpose by unlawful means.

Plaintiffs must prove the following elements by a preponderance of the evidence to establish an alleged conspiracy:

First, that the alleged conspiracy existed;

Second, that there was a "large and unexplained payment" from AstraZeneca to Teva;

Third, that the "large and unexplained" payment was in exchange for Teva delaying the sale of a generic Nexium product; and

Fourth, that AstraZeneca and Teva knowingly became a member of that conspiracy; knowingly means voluntarily and intentionally, and not because of mistake or accident or other innocent reason.

If you do determine that the element of conspiracy is satisfied with respect to the settlement between Teva and AstraZeneca, you must go on to consider the other elements of the claim based on that Teva settlement to determine whether it reduced competition in an unlawful manner. Only if you determine that the individual Teva settlement was unlawful will it be necessary to go on to consider the other claim of conspiracy that plaintiffs allege, that is an overarching conspiracy in which the generic defendants not only agreed with AstraZeneca to settle each of their cases, but also agreed with each other and AstraZeneca to delay competition.

Defendants' Proposed Final Instruction No. 28: Sherman Act Section 1 – Overarching Conspiracy As to All Defendants

In addition to alleging a two-party conspiracy between Teva and AstraZeneca, the Plaintiffs also allege that AstraZeneca, Teva, Ranbaxy and Dr. Reddy's participated in an overarching conspiracy to delay the launch of generic Nexium. A conspiracy is an agreement by two or more persons to accomplish some unlawful purpose or to accomplish a lawful purpose by unlawful means.

There is no claim before you that the separate settlements with Ranbaxy and Dr. Reddy's caused any harm to competition or were unlawful. There is thus no claim that the Ranbaxy settlement or the Dr. Reddy's settlement meets the two-party conspiracy test for the Teva settlement just described.

With respect to the overarching conspiracy, the Plaintiffs must first prove both of the following elements by a preponderance of the evidence:

First, that the alleged conspiracy existed; and

Second, that each Defendant knowingly became a member of that conspiracy; knowingly means voluntarily and intentionally, and not because of mistake or accident or other innocent reason.

A conspiracy is a kind of "partnership" in which each person found to be a member of the conspiracy is liable for all acts and statements of the other members made during the existence of and in furtherance of the conspiracy. To create such a relationship, two or more persons must enter into an agreement that they will act together for some unlawful purpose or to achieve a lawful purpose by unlawful means.

To establish the existence of an overarching conspiracy, the evidence must show that the alleged members of the conspiracy in some way came to an agreement to accomplish a common purpose. It is undisputed that each generic Defendant entered into an agreement with AstraZeneca to settle patent litigation. Those two-party agreements, standing alone, are not sufficient evidence of the overarching conspiracy.

Rather, in addition to the settlement agreements with AstraZeneca, Plaintiffs must show for each of the generic defendants, that is, individually for each of Teva, Ranbaxy, and DRL, that it conspired with AstraZeneca and at least one of the other generic defendants.

Conduct that is as consistent with independent action as it is with illegal conspiracy does not, standing alone, support an inference of an antitrust conspiracy. Plaintiffs must produce evidence that is not only consistent with conspiracy, but tends to exclude the possibility of independent action, that is, it excludes the possibility that the individual defendants took the actions they did for their own independent reasons.

In this case, there is no direct proof of a conspiracy, such as communications between the generic Defendants about the terms of their agreements, or indirect messages amongst the generic Defendants coordinated by AstraZeneca or otherwise. Instead, you will decide whether Plaintiffs have proven the existence of the alleged conspiracy through the circumstances or by the acts of the alleged conspirators. This kind of proof is allowed in antitrust cases, but is subject to limitations I will describe in a moment. You may infer the existence of an agreement from what you find the alleged conspirators actually did, as well as from the words they used. Mere similarity of conduct among various persons, however, or the fact that they may have associated with one another does not establish the existence of a conspiracy unless the evidence tends to exclude the possibility that the persons were acting independently. If they acted similarly but independently of one another, without any agreement among them, then there would not be a conspiracy.

The presence of similar contractual language in each settlement is not, standing alone, proof of conspiracy. If the Defendants acted independently in response to similar market forces or similar facts, that does not constitute a conspiracy. In other words, if Ranbaxy, Teva or DRL acted similarly but independently of each other in agreeing to a May 27, 2014 entry date and to settle their patent litigation, then there would not be an overarching conspiracy.

In determining whether an agreement has been proved, you must view the evidence as a whole and not piecemeal. In considering the evidence, you first should determine whether or not the alleged conspiracy existed. If you conclude that the conspiracy did exist, you should next determine whether each defendant knowingly became a member of that conspiracy with the intent to further its purposes.

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 1, Instruction 1 (first sentence modified); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986) (eighth paragraph herein); *White v. R.M. Packer Co.*, 635 F.3d 571, 577 (1st Cir. 2011) (quoting *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 768 (1984)) (eighth paragraph herein); *Monsanto Co. v. Spray-Rite Co.*, 465 U.S. 752, 768 (1984); *In re Elevator Antitrust Litig.*, 502 F.3d 47, 51 (2d Cir. 2007) (tenth paragraph herein).

Defendants' Proposed Final Instruction No. 29: Sherman Act Section 1 Overarching Conspiracy – Conscious Parallelism

Plaintiffs contend that the existence of a single overarching conspiracy can be inferred from the fact that AstraZeneca entered into separate settlement agreements with Teva, Ranbaxy and Dr. Reddy's that provide for the entry of generic Nexium on May 27, 2014 (or earlier, under certain circumstances).

The conspiracy provisions of the antitrust laws reach only unlawful agreements. They do not apply to independent decisions, even if they lead to the same anticompetitive result as an actual agreement among market actors. To avoid inadvertently punishing similar, but legal behavior, the law limits the inferences you may draw from circumstantial evidence about the existence of an agreement, combination or conspiracy to restrain trade. It is only agreements to restrain trade that violate the antitrust laws. Similar, but independent conduct, even if it has the same effect as an agreement, does not violate the antitrust laws.

Thus, proof that Ranbaxy, Teva, and Dr. Reddy's acted in a similar fashion or entered into similar agreements with AstraZeneca is insufficient to establish that they actually conspired with each other. The Defendants' behavior may be no more than the result of the exercise of independent judgment in response to identical or similar market conditions. Merely parallel conduct is not sufficient, even if each individual generic had full knowledge, and thus was conscious of what the other generics were doing. Plaintiffs' evidence must tend to exclude the possibility that the alleged conspirators acted independently.

The mere fact that AstraZeneca entered into settlement agreements with Teva, Ranbaxy and Dr. Reddy's that provide for the entry of generic Nexium on May 27, 2014 (or earlier, under certain circumstances) is not, by itself, sufficient to prove the existence of the alleged agreement. Likewise, if Ranbaxy, Teva, or DRL acted similarly, but independently, in agreeing to contractual language in each settlement permitting an entry date before May 27, 2014 if another generic manufacturer were to legally enter the market with a generic version of Nexium before that date, then there would not be a conspiracy. You may consider the Defendants' parallel conduct along with other evidence in deciding whether the Defendants' conduct was the result of an agreement, and not the result of separate decisions made by each defendant on its own.

A business may lawfully enter into a similar settlement of a lawsuit as long as it does so independently and not as part of an agreement with one or more of its competitors with the purpose of restraining trade. So, the fact that Teva or DRL may have known that Ranbaxy had agreed to a May 27, 2014 entry date does not mean they agreed with each other on that date, or with Ranbaxy, on that date.

To establish the existence of an agreement solely by circumstantial evidence, the Plaintiffs must prove by a preponderance of the evidence facts that tend to exclude the possibility that the Defendants acted independently. But the law limits the inferences you may make merely from the fact that multiple parties acted in the same way. You may properly consider the motives each defendant had to act jointly with its co-defendants, rather than independently. You may consider as well as the benefits that joint, rather than separate action could bestow on each

defendant given its circumstances. You may also consider the timing of the alleged decisions to join the conspiracy. While conspirators may join a conspiracy at different times, some later than others, the fact that one or more did not join at the same time may be relevant to whether a given defendant's decision to join the alleged conspiracy may be inferred from purely parallel conduct. It is not the similar conduct that is unlawful, but whether each defendant actually conspired to restrain trade.

Because parallel behavior, even consciously parallel behavior, is legal, Plaintiffs need to prove what we call a "plus factor" that tends to suggest that parallel action was part of a conspiracy or agreement, rather than by the independent choice of each Defendant. *Matsushita*, 475 U.S. at 588; *White v. R.M. Packer*, 635 F.3d at 577.

One plus factor that is alleged in this case is that agreeing to a May 27, 2014 entry date was against the economic interest of the generic Defendants unless all other generic manufacturers who were attempting to bring generic Nexium to market agreed to a May 27, 2014 entry date as well, and that the contingent launch clauses in the settlement agreements were the mechanism for securing the agreement of all the generic manufacturers. Thus, Plaintiffs must prove, as to each of Teva, Ranbaxy, and DRL that the settlements were against their interest, and would not have happened, unless they knew that other generic manufacturers would agree to the same thing.

Therefore, the fact that AstraZeneca has entered into patent litigation settlements with each of Ranbaxy, Teva and DRL that contain the same entry date and other similar provisions, is not, by itself, sufficient to prove the existence of the alleged overarching conspiracy. You must consider the Defendants' settlements along with other evidence in deciding whether each Defendant's conduct was the result of an overarching agreement between all Defendants, and not the result of separate decisions made by each Defendant on its own.

You should consider all of the evidence, as a whole, against the entire background in which the alleged behavior takes place. After considering all of the evidence, if you conclude that the Plaintiffs have failed to carry their burden of proving facts by a preponderance of the evidence that tend to exclude the possibility that each Defendant acted independently, then you must find for that Defendant. Likewise, if you conclude that the Plaintiffs have carried their burden of proving facts that tend to exclude the possibility that certain Defendants acted independently, then you must find for the Plaintiffs and against those certain Defendants on the question of whether those Defendants participated in a conspiracy.

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 554, 557 (2007) ("[M]erely parallel conduct" is not sufficient; the plaintiff's evidence must "tend[] to exclude the possibility" that the alleged conspirators acted independently); *White v. R.M. Packer Co.*, 635 F.3d 571, 575 (1st Cir. 2011); *Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 426 (6th Cir. 2008); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 327 (3d Cir. 2010) ("one cannot plausibly infer a horizontal agreement among a broker's insurer-partners from the mere fact that each insurer entered into a similar contingent commission agreement with the broker.");

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 1, Instruction 2 (modified); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986); *Monsanto* v. *Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984); *White v. R.M. Packer Co.*, 635 F.3d 571, 580 (1st Cir. 2010).

Defendants' Proposed Final Instruction No. 30: Sherman Act Section 1 Overarching Conspiracy – Benefits to Generic Defendants

With respect to Plaintiffs' allegation that all four Defendants entered into a single overarching conspiracy to restrain trade in a relevant market, Plaintiffs must prove that each generic Defendant, that is, each of Teva, Ranbaxy, and Dr. Reddy's, individually benefitted from the participation of the other generic Defendants. If Plaintiffs do not make such a showing by a preponderance of the evidence, you cannot find that all four Defendants entered into a single conspiracy to restrain trade.

Howard Hess Dental Labs, Inc. v. Dentsply, Int'l, Inc., 602 F.3d 237, 255 (3d Cir. 2010) (declining to find horizontal conspiracy in the absence of benefit to spokes); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 328 (3d Cir. 2010) (same).

Defendants' Proposed Final Instruction No. 31: Sherman Act Section 1 – Participation and Intent

Before you can find that any Defendant was a member of any conspiracy alleged by Plaintiffs, the evidence must show that the Defendant knowingly joined in the unlawful plan at its inception or at some later time with the intent to advance or further some object or purpose of the conspiracy.

To act knowingly means to act voluntarily and intentionally, and not because of mistake or accident or other innocent reason. A person may become a member of a conspiracy without full knowledge of all the details of the conspiracy, the identity of all its members, or the parts they played. Knowledge of the essential nature of the plan is enough. On the other hand, a person who has no knowledge of a conspiracy, but happens to act in a way that furthers some object or purpose of the conspiracy, does not thereby become a conspirator.

A person who knowingly joins an existing conspiracy, or who participates only in part of a conspiracy with knowledge of the overall conspiracy, is just as responsible as if he had been one of those who formed or began the conspiracy and participated in every part of it.

The membership of a Defendant in a conspiracy must be based only on evidence of its own statements or conduct. In determining whether any Defendant was a member of the alleged conspiracy, you should consider only the evidence of that particular Defendant's statements and conduct, including any evidence of that Defendant's knowledge or lack of knowledge, status, and participation in the events involved, and any other evidence of participation in the conspiracy alleged.

If you find that an alleged conspiracy existed, then the acts and statements of the conspirators are binding on all of those whom you find were members of the conspiracy. But actions or statements of any conspirators that were not done or made in furtherance of the conspiracy, or that were done or made before its existence or after its termination, may be considered as evidence only against the person who made them.

One a person is found by you to be a member of a conspiracy, he or she is presumed to remain a member and is responsible for all actions taken by all conspirators during and in furtherance of the conspiracy until it is show that the conspiracy has been completed or abandoned.

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 1, Instruction 4; *United States v. Rawwad*, 807 F.2d 294, 297 (1st Cir. 1986) (fourth paragraph, Defendant's own actions and statements are only proper evidence for that Defendant's joining a conspiracy).

Defendants' Proposed Final Instruction No. 32: Sherman Act 1 – Exchange for Delay

Another element of the alleged conspiracies that that Plaintiffs must prove by a preponderance of the evidence is that the alleged "large and unexplained payment" was made in exchange for Teva delaying the sale of a generic Nexium product

During its patent litigation against Teva, AstraZeneca contended that its patents prevented Teva from marketing generic Nexium until the patents expired. The earliest any of the Nexium Patents expired was May 27, 2014. The others expired in 2015 and 2018. As I have told you, Teva contended that the patents should not keep it from marketing its generic Nexium product because, Teva claimed, the patents were invalid and/or not infringed.

The antitrust laws do not prevent companies from settling this kind of patent litigation. They may settle, for example, by allowing the generic manufacturer to market its products prior to the patent's expiration.

Therefore, the fact that the AstraZeneca-Teva settlement agreement did not provide for an immediate launch of generic Nexium is not by itself proof of an exchange for delay. Rather, plaintiffs must prove by a preponderance of the evidence that:

> (1) AstraZeneca and Teva's selection of May 27, 2014 as the licensed Teva launch date was made in exchange for a large and unexplained payment from AstraZeneca to Teva, and not merely the result of the factors relating to the litigation, including how long it would take and the probable outcome, the parties' assessments regarding the likelihood and timing of FDA approvals, or some other legitimate business purpose; and
>
> (2) The selection of a May 27, 2014 entry date in fact achieved a delay in the lawful sale of Teva's generic Nexium that would have occurred in the absence of the licensed entry date – in other words that at the time of settlement AstraZeneca and Teva expected that Teva would have been willing, able and legally permitted to enter the market before May 27, 2014.

FTC v. Actavis, 133 S. Ct. 2223, 2236-37 (2013).

Defendants' Proposed Final Instruction No. 33: Sherman Act Section 1 – Relevant Market

An essential element of Plaintiff's two conspiracy claims is that the alleged conspiracy unreasonably restrained trade in a valid relevant antitrust market.

Plaintiffs must show that the alleged harm to competition occurred in an identified market, known as a "relevant market." It is Plaintiffs' burden to prove the existence of a relevant market by a preponderance of the evidence.

To make this judgment, you must be able to determine what, if any, economic forces restrain AstraZeneca's freedom to set prices for the drug Nexium. The most likely and most important restraining force will be the actual and potential competition from other firms and their products. This includes all firms and products that act as restraints on AstraZeneca's power to set prices as it pleases. All of the firms and products that exert this restraining force are within the relevant market.

There are two aspects you must consider in determining whether Plaintiffs have met their burden to prove the relevant market by a preponderance of the evidence. The first is the relevant product market; the second is the relevant geographic market. The parties agree that the relevant geographic market is the entire United States.

Defendants' Proposed Final Instruction No. 34: Sherman Act Section 1 – Relevant Product Market

The basic idea of a relevant product market is that the products within it are reasonable substitutes for each other from the buyer's point of view; that is, the products compete with each other. In other words, the relevant product market includes the products that a consumer believes are reasonably interchangeable or reasonable substitutes for each other. This is a practical test with reference to actual behavior of buyers and marketing efforts of sellers. Products need not be identical or precisely interchangeable as long as they are reasonable substitutes for each other. Thus, for example, if consumers seeking to cover leftover food for storage considered certain types of flexible wrapping material—such as aluminum foil, cellophane, or even plastic containers—to be reasonable alternatives, then all those products would be in the same relevant product market.

With respect to the relevant product market in a matter involving pharmaceuticals, the relevant consumers may include physicians who prescribe drugs, as well as patients, hospitals, and third party payors who purchase and/or reimburse for drug purchases.

To determine whether products are reasonable substitutes for each other, you should consider whether a small but significant permanent increase in the price of one product would result in a substantial number of customers switching from that product to another. Generally speaking, a small but significant permanent increase in price is approximately a five percent increase in price not due to external cost factors, but you may conclude in this case that some other percentage is more applicable to the product at issue. If you find that such switching would occur, then you may conclude that the products are in the same product market.

In evaluating whether various products are reasonably interchangeable or are reasonable substitutes, you may also consider: (1) consumers' views on whether the products are interchangeable; (2) the relationship between the price of one product and sales of another; (3) the presence or absence of specialized vendors; (4) the perceptions of either industry or the public as to whether the products are in separate markets; (5) the views of the plaintiff and defendant regarding who their respective competitors are; and (6) the existence or absence of different consumer groups or distribution channels.

In this case, Plaintiffs contend that the relevant product market consists of only branded and generic Nexium. By contrast, Defendants contend that the relevant product market also includes numerous other heartburn drugs, including branded, generic and over-the-counter drugs in the heartburn category or the specific Proton Pump Inhibitor (or "PPI") class. If you find that Plaintiffs have proven by a preponderance of the evidence that the relevant product market consists only of the market for branded and generic Nexium, then you should answer "Yes" to Question 1 on the Verdict Form and consider the remaining elements of Plaintiffs' claims. However, if you find that Plaintiffs have failed to prove such a market by a preponderance of the evidence, then you then you should answer "No" to Question 1 on the Verdict Form and proceed to the end of the Verdict Form.

Model Jury Instructions in Civil Antitrust Cases, ABA Section of Antitrust Law (2005 ed.), Sherman Act Section 2, Instruction 4; *Geneva Pharmaceuticals Technology Corp. v. Barr Laboratories, Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (second paragraph herein) ("We note that there is not just one relevant consumer group, and are mindful to consider the impact that patients, doctors, third-party payors, wholesalers, and chain pharmacies can have on the price and output of [a drug].").

Defendants' Proposed Final Instruction No. 35: Sherman Act Section 1– Harm to Competition in Relevant Market

As I have been describing, one essential element of Plaintiffs' conspiracy claims is that the alleged conspiracy unreasonably restrained trade in a valid relevant antitrust market. If you find that Plaintiffs have proven by a preponderance of the evidence that the relevant product market consists only of branded and generic Nexium, then you should consider whether the alleged conspiracy has resulted in a substantial harm to competition in that market.

A harmful effect on competition, or competitive harm, refers to a reduction in competition that results in the loss of some of the benefits of competition, such as lower prices, increased output, and higher product quality. If the challenged conduct has not resulted in higher prices, decreased output, lower quality, or the loss of some other competitive benefit, then there has been no competitive harm and you should find that the challenged conduct was not unreasonable.

Plaintiffs allege that each alleged conspiracy resulted in a substantial harm to competition by delaying the entry of generic Nexium into the marketplace until May 27, 2014.

As I previously instructed you, the Court has ruled that there is insufficient evidence to show that either Ranbaxy or Dr. Reddy's would have received final FDA approval of a generic Nexium product prior to May 27, 2014, or that if it had approval one of these companies would have actually entered the market with generic Nexium prior to May 27, 2014. Therefore, you may not consider the possibility of either Ranbaxy or Dr. Reddy's entering the marketplace in your deliberations concerning the element of harm to competition in a relevant market. You may only consider whether Teva could have lawfully launched an FDA approved product prior to May 27, 2014 in your deliberations concerning this element.

There cannot be an unlawful restraint of trade when the allegedly suppressed competition would not have been lawful. As I previously instructed you, the FDA must give final approval of a generic drug before it can be sold lawfully in the United States. Tentative approval by the FDA is not sufficient. Thus, in order to prove a substantial harm to competition resulting from the alleged conspiracy, Plaintiffs have the burden to prove by a preponderance of the evidence that, but for the alleged conspiracies, Teva would have received final FDA approval of generic Nexium prior to May 27, 2014.

Defendants contend that Teva's patent litigation settlement with AstraZeneca had no effect on the date on which a generic Nexium product will enter the market, because Teva could not enter the market with a generic Nexium product until Ranbaxy's 180-day exclusivity period either was triggered by Ranbaxy's sale of generic Nexium and then ran its course or was voluntarily relinquished by Ranbaxy. As I previously instructed you, Ranbaxy was the first ANDA applicant to file a certification with respect to generic Nexium. The Hatch-Waxman Act granted Ranbaxy a 180-day period of the right to market its product exclusively without any competition from another ANDA applicant. The period of exclusivity prohibits the FDA from granting final approval of any other generic drug based on the same NDA until the first ANDA filer has marketed its product for 180 days, has waived its right to market its product exclusively,

or has been forfeited. Please refer to Instruction No. [] and apply it in full to your deliberations here.

In addition, as I previously instructed you, a generic drug manufacturer cannot lawfully sell a generic drug if the sale of the generic drug infringes a valid patent. Thus, in order to prove substantial harm to competition resulting from the alleged conspiracy, Plaintiffs have the burden to prove that Teva could have sold generic Nexium prior to May 27, 2014 without infringing a valid Nexium Patent. My prior instruction on this subject, Instruction No. [], applies with equal force here. Please refer to Instruction No. [] and apply it in full to your deliberations here.

Plaintiffs also must demonstrate that, but for the alleged conspiracies, Teva would have actually entered the market with a generic Nexium product prior to May 27, 2014. My prior instruction on this subject, Instruction No. [], applies with equal force here. Please refer to Instruction No. [] and apply it in full to your deliberations here.

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 1, Instruction 3B (excerpt) (modified); Proposed Instruction No. [], *supra* (collecting authorities); *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 23 (D. Mass. 2000) (antitrust injury cannot be based on entry that cannot occur pending the first filer's exclusivity).

21 U.S.C. § 355(a)-(c); 21 U.S.C. § 355(j); *Patent Case Management Judicial Guide*, Federal Judicial Center (2009), *available at* http://www.fjc.gov/public/pdf.nsf/lookup/Patent01.pdf/$file/Patent01.pdf, §§ 10.1, 10.1.1, 10.1.2 (modified); *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 23 (D. Mass. 2000); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, Nos. 06-52 (GMS) & 06-71(GMS), 2010 WL1485328, at *2 (D. Del. Apr. 13, 2010).

Defendants' Proposed Final Instruction No. 36: Sherman Act Section 1 – Rule of Reason Competitive Benefits

If you find that Plaintiffs have proved that any of the challenged restraints resulted in substantial harm to competition in a relevant market, then you next must determine whether that particular restraint also benefits competition in other ways. In this case, the Defendants contend that the challenged restraints benefits competition in at least the following ways:

First, Defendants assert that each of the respective patent litigation settlement agreements, that is, the settlement agreement between AstraZeneca and Teva, the settlement agreement between AstraZeneca and Ranbaxy, and the settlement agreement between AstraZeneca and Dr. Reddy's—individually and collectively—were procompetitive because they allowed for lawful sales of generic Nexium earlier than would have occurred had the underlying patent litigations not settled;

Second, AstraZeneca asserts that the agreements were procompetitive because they protected the valid patents of AstraZeneca. The law encourages invention by awarding patents, and thereby allowing inventors to profit from their inventions. There are great social benefits to investments in drug patents. Accordingly, the goals of competition are served if products that infringe valid patents are kept out of the market, and AstraZeneca contends that each of the generic Defendants' Nexium products infringed valid patents;

Third, Defendants assert that the agreements are procompetitive because they provided the generic manufacturers with access to AstraZeneca technology that was covered by patents that did not expire until as late as 2018, which allowed them to make their generic Nexium products better and cheaper;

Fourth, Defendants assert that each of the respective settlement agreements provided business certainty for the parties and the marketplace; and

Fifth, Defendants assert that each of the respective settlement agreements permitted the Defendants to avoid the expense of prolonged patent litigation, thereby allowing each Defendant to focus more money and company resources toward the development and sale of new and cheaper drugs for consumers.

If you find that any of the challenged restraints do result in competitive benefits, then you also must consider whether that restraint was reasonably necessary to achieve the benefits. If the Plaintiffs prove that the same benefits could have been readily achieved by other, reasonably available alternative means that create substantially less harm to competition, then they cannot be used to justify that restraint.

Adapted from ABA Model Jury Instructions in Civil Antitrust Cases, A-10 (2005 ed.).

Defendants' Proposed Final Instruction No. 37: Sherman Act Section 1 Conspiracy Claims – Rule of Reason Balancing the Competitive Benefits

If you find that any of the challenged restraints was reasonably necessary to achieve competitive benefits, then you must balance those competitive benefits against the competitive harm resulting from the same restraint. If the competitive harm substantially outweighs the competitive benefits, then the challenged restraint is unreasonable. If the competitive harm does not substantially outweigh the competitive benefits, then the challenged restraint is not unreasonable.

Adapted from ABA Model Jury Instructions in Civil Antitrust Cases, A-12 (2005 ed.).

Defendants' Proposed Final Instruction No. 38: Sherman Act Section 2 – Monopolization – Elements

Plaintiffs allege that Defendant AstraZeneca unlawfully monopolized a relevant market that Plaintiffs allege consists only of generic and branded Nexium. Plaintiffs do not allege a monopolization claim against Ranbaxy, Teva, or Dr. Reddy's. Plaintiffs must prove each of the following elements by a preponderance of the evidence:

First, that the alleged market is a valid relevant antitrust market;

Second, that AstraZeneca possessed monopoly power in that market;

Third, that AstraZeneca "willfully" acquired or maintained monopoly power in that market by engaging in anticompetitive conduct; and

Fourth, that but for AstraZeneca's anticompetitive conduct, Teva would have lawfully launched a final FDA approved generic Nexium product prior to May 27, 2014.

Model Jury Instructions in Civil Antitrust Cases, ABA Section of Antitrust Law (2005 ed.), Sherman Act Section 2, Monopolization, Instruction 1 (modified to address bifurcation issues and the allegations made in this case; interstate commerce is not a disputed issue).

Defendants' Proposed Final Instruction No. 39: Sherman Act Section 2 – Monopolization – Monopoly Power Defined

To prove any of their claims, one of the elements Plaintiffs must prove is that Defendant AstraZeneca has monopoly power in a relevant antitrust market.

Monopoly power is the power to control prices and exclude competition in a relevant antitrust market. More precisely, a firm is a monopolist if it can profitably raise prices substantially above the competitive level for a significant period of time. However, monopoly power, in and of itself, is not unlawful.

I will provide further instructions about how you may determine whether Plaintiffs have met their burden of proving monopoly power in a relevant market.

Model Jury Instructions in Civil Antitrust Cases, ABA Section of Antitrust Law (2005 ed.), Sherman Act Section 2, Instruction 2 (sequence of sentences in instruction modified).

Defendants' Proposed Final Instruction No. 40: Sherman Act Section 2 – Monopolization – Relevant Market – General

Plaintiffs must prove by a preponderance of the evidence that Defendant AstraZeneca had monopoly power in a relevant market. Defining the relevant market is essential because you are required to make a judgment about whether Defendant AstraZeneca had monopoly power in a properly defined economic market.

My instructions concerning the definition of "relevant market" and "relevant product market" (Instructions No. []) apply with equal force here. As I instructed you earlier, if you find that Plaintiffs have proven by a preponderance of the evidence that the relevant product market consists only of the market for branded and generic Nexium, then you should consider the remaining elements of Plaintiffs' claim. However, if you find that Plaintiffs have failed to prove such a market by a preponderance of the evidence, then you then you should not consider the remaining elements of Plaintiffs' claim.

Defendants' Proposed Final Instruction No. 41: Sherman Act Section 2 – Monopolization – Existence of Monopoly Power

If you find that Plaintiffs have proved by a preponderance of the evidence that the relevant market is the market for branded and generic Nexium, then I instruct you that AstraZeneca had monopoly power in the relevant market.

If, however, you find that Plaintiffs have failed to prove by a preponderance of the evidence that the relevant market is the market for branded and generic Nexium, then I instruct you that AstraZeneca did not have monopoly power in the relevant market.

Defendants' Proposed Final Instruction No. 42: Sherman Act Section 2 – Monopolization – Willful Acquisition or Maintenance of Monopoly Power

The next element Plaintiffs must prove is that Defendant AstraZeneca willfully acquired or maintained monopoly power through anticompetitive acts or practices.

You may not find that AstraZeneca willfully acquired or maintained monopoly power if it has acquired or maintained that power solely through the exercise of superior foresight and skill; or because of natural advantages such as unique geographic proximity to raw materials or markets; or because of economic or technological efficiency, including efficiency resulting from scientific research; or by obtaining a lawful patent; or because changes in cost or taste have driven out all but one supplier.

Mere possession of monopoly power, if lawfully acquired, does not violate the antitrust laws. A monopolist may compete aggressively without violating the antitrust laws, and a monopolist may charge monopoly prices without violating the antitrust laws. A monopolist's conduct only becomes unlawful when it involves anticompetitive acts.

As I instructed you previously, a patent is a lawful monopoly conveyed by the U.S. Government. You may not conclude that AstraZeneca unlawfully acquired or maintained monopoly power in any relevant market unless Plaintiffs prove that Teva's generic Nexium would not infringe any valid Nexium Patent.

Defendants' Proposed Final Instruction No. 43: Sherman Act Section 2 – Monopolization –Willful Acquisition or Maintenance of Monopoly Power – Alleged Anticompetitive Act

Plaintiffs allege that AstraZeneca engaged in an anticompetitive act by entering into a patent litigation settlement agreement with Teva in which AstraZeneca made a large and unexplained reverse payment to Teva in exchange for a delay in the entry of Teva's generic Nexium into the marketplace. This is the only allegedly anticompetitive conduct you may consider with respect to Plaintiffs' monopolization claims.

AstraZeneca also entered into settlement agreements with Defendants Dr. Reddy's and Ranbaxy. I instruct you that you may not consider either of those settlements with respect to Plaintiffs' monopolization claims. The only settlement agreement you may consider with respect to Plaintiffs' monopolization claims is the Nexium patent infringement case settlement agreement between AstraZeneca and Teva.

Instruction based on Court's grant of summary judgment for defendants with respect to all substantive claims involving Dr. Reddy's (Dkt. No. 857) and Court's grant of summary judgment with respect to all substantive claims arising from AstraZeneca/Ranbaxy settlement based on Plaintiffs' lack of evidence of causation (Dkt. No. 857).

Defendants' Proposed Final Instruction No. 44: Sherman Act Section 2 – Attempt to Monopolize –Elements

Plaintiffs also allege that AstraZeneca unlawfully attempted to monopolize the alleged relevant market. Plaintiffs must prove each of the following elements by a preponderance of the evidence:

First, that AstraZeneca engaged in anticompetitive conduct;

Second, that AstraZeneca had a specific intent to monopolize a valid relevant antitrust market;

Third, that there was a dangerous probability that AstraZeneca would achieve its goal of monopoly power in a relevant market; and

Fourth, that but for AstraZeneca's anticompetitive conduct, Teva would have lawfully launched a final FDA approved generic Nexium product prior to May 27, 2014.

Model Jury Instructions in Civil Antitrust Cases, ABA Section of Antitrust Law (2005 ed.), Sherman Act Section 2, Attempt to Monopolize, Instruction 1 (modified to address bifurcation issues and the allegations made in this case) (interstate commerce is not a disputed issue).

Defendants' Proposed Final Instruction No. 45: Sherman Act Section 2 – Attempt to Monopolize – Relevant Market

An essential element of Plaintiffs' attempt to monopolize claim is a relevant antitrust market.

Plaintiffs must show that the alleged attempt to monopolize occurred in an identified market, known as a "relevant market." It is Plaintiffs' burden to prove the existence of a relevant market by a preponderance of the evidence.

My instructions concerning the definition of "relevant market" and "relevant product market" (Instructions No. []) apply with equal force here. As I instructed you earlier, if you find that Plaintiffs have proven by a preponderance of the evidence that the relevant product market consists only of the market for branded and generic Nexium, then you should consider the remaining elements of Plaintiffs' claim. However, if you find that Plaintiffs have failed to prove such a market by a preponderance of the evidence, then you then you should not consider the remaining elements of Plaintiffs' claim.

Defendants' Proposed Final Instruction No. 46: Sherman Act Section 2 – Attempt to Monopolize – Anticompetitive Conduct

It is not sufficient for plaintiffs to prove that defendant AstraZeneca intended to monopolize the relevant market. Plaintiffs must also show that AstraZeneca engaged in anticompetitive conduct, coupled with an intent to monopolize and a dangerous probability that AstraZeneca would succeed.

Plaintiffs allege that AstraZeneca engaged in an anticompetitive act by entering into a patent litigation settlement agreement with Teva in which AstraZeneca made a large and unexplained reverse payment to Teva in exchange for a delay in the entry of Teva's generic Nexium into the marketplace. This is the only allegedly anticompetitive conduct you may consider with respect to Plaintiffs' monopolization claims. You may not consider AstraZeneca's settlements with either Ranbaxy or Dr. Reddy's with respect to the attempt to monopolize claim. My prior instructions on this subject, Instructions No. [] through [], apply with equal force here. Please refer to Instruction Nos. [] through [] and apply them in full to your deliberations here.

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 2, Attempt to Monopolize, Instruction 2 (cross-referencing related instructions); Dkt. No. 857.

Defendants' Proposed Final Instruction No. 47: Sherman Act Section 2 – Attempt to Monopolize – Specific Intent

The next element that plaintiffs must prove is that defendant AstraZeneca had a specific intent to monopolize a relevant market.

If you find that Plaintiffs have proven that the relevant market is the market for branded and generic Nexium, you must then decide whether AstraZeneca had the specific intent to monopolize that market. In other words, you must decide if the evidence shows that AstraZeneca acted with the conscious aim of acquiring the power to control prices and to exclude or destroy competition in the relevant market.

There are several ways in which a plaintiff may prove that a defendant had the specific intent to monopolize. There may be evidence of direct statements of the defendant's intent to obtain a monopoly in the relevant market. Such proof of specific intent may be established by documents prepared by responsible officers or employees of the defendant at about the time of the agreement or by testimony concerning statements of responsible officers or employees of the defendant. However, you should be careful to distinguish between a defendant's intent to compete vigorously (which is perfectly legal), which may be accompanied by aggressive language, and a true intent to acquire monopoly power by using anticompetitive means.

Even if you decide that the evidence does not prove directly that AstraZeneca actually intended to obtain a monopoly, specific intent may be inferred from what the defendant did. Plaintiffs allege that AstraZeneca engaged in anticompetitive conduct by entering into a patent litigation settlement agreement in which AstraZeneca made a large and unexplained payment to Teva in exchange for delay in the entry of Teva's generic Nexium into the marketplace. This is the only allegedly anticompetitive conduct you may consider with respect to Plaintiffs' attempt to monopolize claims. You may not consider AstraZeneca's settlements with either Ranbaxy or Dr. Reddy's with respect to the attempt to monopolize claim. My prior instructions, Instructions No. Instructions No. [] through [] apply with equal force here. Please refer to Instruction Nos. [] through [] and apply them in full to your deliberations here.

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 2, Attempt to Monopolize, Instruction 3 (modified based on allegations in this case); Dkt. No. 857.

Defendants' Proposed Final Instruction No. 48: Sherman Act Section 2 – Attempt to Monopolize – Dangerous Probability of Success

If you find that AstraZeneca had the specific intent to achieve a monopoly and engaged in significant anticompetitive conduct, you also must determine if the evidence shows the next element of attempt to monopolize: namely, that there was a dangerous probability that AstraZeneca would succeed in achieving market power if it continued to engage in the same or similar conduct.

In determining whether there was a dangerous probability that AstraZeneca would acquire the ability to control price in the market, you should consider such factors as AstraZeneca's market share, the trend in AstraZeneca's market share, whether the barriers to entry into the market made it difficult for competitors to enter the market, and the likely effect of any anticompetitive conduct on defendant's share of the market.

The purpose of looking at these and other factors is to determine whether there was a dangerous probability that AstraZeneca would ultimately acquire monopoly power. A dangerous probability of success does not mean that success was nearly certain, but it does mean that there was a substantial and real likelihood that AstraZeneca would ultimately acquire monopoly power.

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 2, Attempt to Monopolize, Instruction 4 (modified).

Defendants' Proposed Final Instruction No. 49: Sherman Act Section 2 Conspiracy Claims – Conspiracy to Monopolize

Plaintiffs allege a conspiracy to monopolize in violation of Section 2 of the Sherman Act, which declares unlawful every conspiracy to monopolize interstate commerce. As with their conspiracy in restraint of trade claims, Plaintiffs allege both a conspiracy between AstraZeneca and Teva, and an overarching conspiracy against all Defendants (AstraZeneca, Teva, Ranbaxy and Dr. Reddy's).

With respect to the claim of conspiracy to monopolize, Plaintiffs must prove by a preponderance of the evidence each of the following elements with respect to the Defendant you are considering:

First, that an agreement or mutual understanding between two or more Defendants to maintain AstraZeneca's monopoly power in a valid relevant antitrust market existed;

Second, that each Defendant knowingly—that is voluntarily and intentionally—became a party to that agreement or mutual understanding;

Third, that each Defendant specifically intended that the parties to the agreement would maintain AstraZeneca's monopoly power in a relevant antitrust market;

Fourth, that each Defendant committed an overt act in furtherance of the conspiracy; and

Fifth, that, but for the alleged conspiracy to monopolize, Teva would have lawfully launched a final FDA approved generic Nexium product prior to May 27, 2014.

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 2, Conspiracy to Monopolize, Instruction 1 (modified).

Defendants' Proposed Final Instruction No. 50: Sherman Act Section 2 Conspiracy Claims – Conspiracy to Monopolize – Existence of a Conspiracy

Plaintiffs allege that Defendant AstraZeneca conspired with Defendants Teva, Ranbaxy and Dr. Reddy's to maintain AstraZeneca's monopoly power in the relevant market by delaying the entry of generic Nexium into the marketplace.

My prior Instructions concerning the subject of conspiracy—Instructions No. [] through [] apply with equal force here. Please refer to Instruction Nos. [] through [] and apply them in full to your deliberations here. I instruct you that Plaintiffs only allege a single overarching conspiracy among all four defendants—AstraZeneca, Teva, Ranbaxy and Dr. Reddy's—in their conspiracy to monopolize claim.

See ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 2, Conspiracy to Monopolize, Instruction 2 (cross-referencing pertinent conspiracy instructions).

Defendants' Proposed Final Instruction No. 51: Sherman Act Section 2 Conspiracy Claims – Conspiracy to Monopolize – Specific Intent

If you determine that there was a conspiracy among AstraZeneca and Teva and/or an overarching agreement among all Defendants to maintain AstraZeneca's monopoly of a relevant antitrust market, you must then decide, as to each Defendant, whether plaintiffs have proven that that Defendant had specifically intended that AstraZeneca would maintain monopoly power in the relevant market. In other words, you must decide whether the evidence shows that the Defendant entered into the agreement with the conscious aim of using anticompetitive conduct to maintain AstraZeneca's power to control prices and exclude competition in the relevant market. Neither proof of use of the power to exclude, nor proof of actual exclusion of existing or potential competitors, is essential to sustain the charge of conspiracy to monopolize.

Because Plaintiffs must prove specific intent to monopolize a valid relevant market, if Plaintiffs do not prove a valid specific relevant market, you cannot find that specific intent is present.

There are several ways in which a plaintiff may prove that a defendant had the specific intent to maintain AstraZeneca's monopoly of a relevant antitrust market. There may be evidence of direct statements of the defendant's intent to use anticompetitive means to maintain AstraZeneca's monopoly power in the market. Such proof of specific intent may be established by documents prepared by responsible officers or employees of the defendant at about the time of the agreement or by testimony concerning statements of responsible officers or employees of the defendant. However, you should be careful to distinguish between a specific intent to compete vigorously (which is perfectly legal), which may be accompanied by aggressive language, and a specific intent to monopolize by using anticompetitive conduct.

Even if you decide that the evidence does not prove directly that a Defendant actually intended to maintain AstraZeneca's monopoly of a relevant antitrust market by using anticompetitive conduct, specific intent may be inferred from what the Defendant did. Plaintiffs allege that Defendants engaged in anticompetitive conducts by entering into patent litigation settlement agreements, including one in which AstraZeneca made a large and unexplained payment to Teva in exchange for a delay the entry of Teva's generic Nexium into the marketplace. This is the only allegedly anticompetitive conduct claimed by Plaintiffs. It is the only allegedly anticompetitive conduct you may consider. You may not consider the settlement agreements between AstraZeneca and Ranbaxy or Dr. Reddy's with respect to the question whether AstraZeneca agreed to make a large and unexplained reverse payment to a generic defendant.

My prior instructions on this subject, Instructions No. Instructions No. [] through [] apply with equal force here. Please refer to Instruction Nos. [] through [] and apply them in full to your deliberations here.

ABA Model Jury Instructions in Civil Antitrust Cases, 2005 edition, Sherman Act-Section 2, Conspiracy to Monopolize, Instruction 4 (modified); Dkt. No. 857.

Defendants' Proposed Final Instruction No. 52: Sherman Act Section 2 Conspiracy Claims – Conspiracy to Monopolize – Overt Act

Plaintiffs also must prove, with respect to the defendant you are considering, that the defendant committed an overt act in furtherance of the alleged conspiracy to monopolize.

An overt act is any act knowingly committed by a conspirator in an effort to accomplish some purpose of the conspiracy. The overt act must take place during the period of the alleged conspiracy.

First Circuit Pattern Criminal Jury Instruction 4.18.371(1) (modified for civil claim); *ABA Model Jury Instructions in Civil Antitrust Cases*, 2005 edition, Sherman Act-Section 2, Conspiracy to Monopolize, Instruction 1 (first sentence herein).

Defendants' Proposed Final Instruction No. 53: Sherman Act Section 2 Conspiracy Claims – Conspiracy to Monopolize – Relevant Market and Market Power

An essential element of Plaintiff's conspiracy claim is that the alleged conspiracy involved a relevant antitrust market.

It is Plaintiffs' burden to prove the existence of a relevant market by a preponderance of the evidence.

My instructions concerning the definition of "relevant market" and "relevant product market" (Instructions No. []) apply with equal force here. As I instructed you earlier, if you find that Plaintiffs have proven by a preponderance of the evidence that the relevant product market consists of only branded and generic Nexium, then you should consider the remaining elements of Plaintiffs' claim. If you find that Plaintiffs have proved by a preponderance of the evidence that the relevant market consists only of branded and generic Nexium, then I instruct you that AstraZeneca had monopoly power in the relevant market.

If, however, you find that Plaintiffs have failed to prove by a preponderance of the evidence that the relevant market consists only of branded and generic Nexium, then I instruct you that AstraZeneca did not have monopoly power in the relevant market. You should not consider the remainder of Plaintiffs' claim.

See Fraser v. Major League Soccer, 284 F.3d 47, 68 (1st Cir. 20020 ("[T]here are also a number of decisions that say that a relevant market is necessary [with respect to a conspiracy to monopolize claim]. That is also the view of the more persuasive commentary, including the most respected of the antitrust treatises. . . . [W]e lean toward this view as a general matter . . . .") (collecting authorities); *ABA Model Jury Instructions in Civil Antitrust Cases*, 2005 edition, Sherman Act-Section 2, Conspiracy to Monopolize, Instruction 3 (cross-referencing pertinent instructions concerning monopoly power).

Defendants' Proposed Final Instruction No. 54: Sherman Act – All Claims
No Duty to Deal on Hypothetical More Procompetitive Terms

In this case you have heard much about alleged agreements between the Defendants, and about alternate agreements that Plaintiffs allege might possibly have occurred between some of the Defendants.

The antitrust laws do not require that any party, nor any Defendant, enter into a business agreement with another party or to have entered into an alternate agreement with a party in order to create more competition, lower prices, or to benefit consumers. This is because the antitrust laws do not, as a general matter, restrict the long recognized right of a business or manufacturer engaged in an entirely private business to freely exercise his own independent discretion as to parties with whom he will deal.

Accordingly, a Defendant's conduct is not unlawful under the antitrust laws merely because one could hypothesize or imagine an agreement or alternate agreement between some of the Defendants that might result in more competition. The antitrust laws do not require the Court, or you as members of the jury, to act as central planners, identifying the proper terms for dealing between parties -- that is not a role for you or the Court to perform.

You are therefore instructed not to enforce any hypothetical agreement between the Defendants that you imagine they could have made or wish they would have entered into instead of the agreements that have been alleged in this case. Rather, you are to determine whether the acts alleged are unlawful and anticompetitive in accordance with the instructions I am giving to you today.

Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, 540 U.S. 398, 407-11 (2004).

Defendants' Proposed Final Instruction No. 55: Sherman Act – All Claims Causation

For all of Plaintiffs' claims, Plaintiffs also have the burden of proving the element of causation by a preponderance of the evidence. That is, Plaintiffs must prove that Teva would have lawfully launched a generic Nexium product in the United States market prior to May 27, 2014 but for the anticompetitive conduct alleged by Plaintiffs.

Plaintiffs must prove four elements by a preponderance of the evidence to establish causation:

(1) that, but for the alleged anticompetitive conduct, Teva would have received final FDA approval of generic Nexium prior to May 27, 2014;

(2) that Teva could have sold generic Nexium prior to May 27, 2014 without infringing any valid Nexium Patent;

(3) that, but for the alleged anticompetitive conduct, Teva would have had the ability to manufacture generic Nexium in commercially sufficient quantities prior to May 27, 2014; and

(4) that, but for the alleged anticompetitive conduct, Teva would have actually entered the market with generic Nexium prior to May 27, 2014.

As I have previously instructed you, the Court has ruled that there is insufficient evidence to create any genuine factual issue as to whether either Ranbaxy or Dr. Reddy's would have received final FDA approval for generic Nexium prior to May 27, 2014. The Court also has ruled that there is insufficient evidence to create any genuine factual issue as to whether either Ranbaxy or Dr. Reddy's would have actually entered the market with generic Nexium prior to May 27, 2014. Therefore, you may not consider the possibility of either Ranbaxy or Dr. Reddy's launching a generic Nexium product in your deliberations concerning the element of causation. You may consider only the possibility of whether Teva could have lawfully launched in your deliberations concerning the element of causation.

There cannot be causation when the allegedly suppressed competition would not have been lawful. As I have instructed you, before a generic drug can be lawfully sold in the United States, the FDA must give final approval for sale. Tentative approval by the FDA is not sufficient. Thus, Plaintiffs have the burden to prove by a preponderance of the evidence that, but for the alleged anticompetitive conduct, Teva would have received final FDA approval for generic Nexium prior to May 27, 2014.

Defendants contend that Teva's patent litigation settlement agreement with AstraZeneca had no effect on the date on which a generic Nexium product would enter the market, because Teva could not enter the market with a generic Nexium product until Ranbaxy's exclusivity period either was triggered by Ranbaxy's sale of generic Nexium and then ran its course or was

voluntarily relinquished by Ranbaxy. As I previously instructed you, Ranbaxy was the first ANDA applicant to file a certification with respect to generic Nexium. The Hatch-Waxman Act granted Ranbaxy a 180-day period of market exclusivity. The period of exclusivity prohibits the FDA from granting final approval of any other generic drug based on the same NDA until the first ANDA filer's period of exclusivity has either concluded or been relinquished. The first ANDA filer's period of exclusivity can be relinquished only in the circumstances identified in Instruction No. []. Please refer to Instruction No. [] and apply it in full to your deliberations here.

In addition, a generic drug manufacturer cannot lawfully sell a generic drug if the sale of the generic drug infringes a valid patent. Thus, Plaintiffs must prove that the sale of generic Nexium by Teva prior to May 27, 2014 would not have infringed any valid Nexium patent owned by AstraZeneca. My prior instruction on this subject, Instruction No. [], applies with equal force here. Please refer to Instruction No. [] and apply it in full to your deliberations here.

In addition, before a generic drug enters the marketplace, the manufacturer must have the ability to manufacture the drug in commercially sufficient quantities. Thus, Plaintiffs must prove that, but for the alleged anticompetitive conduct, Teva would have had the ability to manufacture generic Nexium in commercially sufficient quantities prior to May 27, 2014.

21 U.S.C. § 355(a); Dkt. No. 857; *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2008) ("[P]laintiffs must prove [the generic] was prepared to sell [the ANDA product] and could have obtained approval from the FDA to do so at some [earlier] point."); *RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) (upholding district court's "causation analysis" where competitor was excluded from the market by lack of regulatory approval rather than the defendant's "allegedly exclusionary conduct"); *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 791–92 (8th Cir. 2006) (upholding dismissal of antitrust claim where injury flowed from federal ban on importation of drugs, not defendants' alleged anticompetitive conduct); *City of Pitt. v. W. Penn Power Co.*, 147 F.3d 256, 268–69 (3d Cir. 1998) ("[A] plaintiff cannot be injured in fact by private conduct excluding him from the market when a statute prevents him from entering that market in any event."); *CBC Cos. v. Equifax, Inc.*, 561 F.3d 569, 573 (6th Cir. 2009) ("No cognizable antitrust injury exists where the alleged injury is a byproduct of the regulatory scheme, or federal law rather than of the defendant's business practices."); *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 23 (D. Mass. 2000) (antitrust injury cannot be based on entry that cannot occur pending the first filer's exclusivity).

Defendants' Proposed Final Instruction No. 56: Foreperson's Role

I come now to the last part of the instructions, the rules for your deliberations.

When you retire you will discuss the case with the other jurors to reach agreement if you can do so. You should select one member of the jury as your foreperson. You shall permit your foreperson to preside over your deliberations, and your foreperson will speak for you here in court.

First Circuit Pattern Criminal Jury Instruction 6.01 (last sentence omitted); Third Circuit Model Civil Jury Instructions, Instruction 3.1 (third sentence herein).

Defendants' Proposed Final Instruction No. 57: Jurors' Duties and Deliberations

When you retire to the jury room to deliberate, you may take with you my instructions, your notes, and the exhibits that the court has admitted into evidence.

You have two main duties as jurors. The first one is to decide what the facts are from the evidence that you saw and heard here in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way.

Your second duty is to take the law that I give you, apply it to the facts, and decide if, under the appropriate burden of proof, the Plaintiffs have established their claims. It is my job to instruct you about the law, and you are bound by the oath that you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the information that I gave you before and during the trial, and these instructions. All instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not let any bias, sympathy or prejudice that you may feel toward one side or the other influence your decision in any way.

As jurors, you have a duty to consult with each other and to deliberate with the intention of reaching a verdict. Each of you must decide the case for yourself, but only after a full and impartial consideration of all the evidence with your fellow jurors. Listen to each other carefully. In the course of your deliberations, you should feel free to re-examine your own views and to change your opinion based upon the evidence. But you should not give up your honest convictions about the evidence just because of the opinions of your fellow jurors. Nor should you change your mind just for the purpose of obtaining enough votes for a verdict.

When you start deliberating, do not talk to the jury officer, to me, or to anyone but each other about the case. During your deliberations, you must not communicate with or provide any information to anyone by any means in this case. You may not use any electronic devices or media, such as cell phones, smart phones (like Blackberries or iPhones), or computers of any kind; the internet, any internet device, or any text or instant messaging service (like Twitter); or any internet chat room, blog, website, or social networking service (such as Facebook, MySpace, LinkedIn, or YouTube) to communicate to anyone any information about this case or to conduct any research about this case until [you conclude your deliberations].

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, each juror must agree to the verdict. Your verdict must be unanimous.

A form of verdict has been prepared for you. It has a series of questions for you to answer. You will take this form to the jury room and [if] you have reached unanimous agreement as to your verdict, you will fill it in, and have your person date and sign the form. You will then return to the courtroom and your foreperson will give your verdict. Unless I direct you otherwise, do not reveal your answers until you are discharged.

Third Circuit Model Civil Jury Instructions, Instruction 3.1 (modified).

Defendants' Proposed Final Instruction No. 58: Consideration of Evidence

Your verdict must be based solely on the evidence and on the law as I have given it to you in these instructions. However, nothing that I have said or done is intended to suggest what your verdict should be; that is entirely for you to decide.

First Circuit Pattern Criminal Jury Instruction 6.02.

Defendants' Proposed Final Instruction No. 59: Communication with the Court

If it becomes necessary during your deliberations to communicate with me, you may send a note through the jury officer signed by your foreperson or by one or more members of the jury. No member of the jury should ever attempt to communicate with me on anything concerning the case except by a signed writing, and I will communicate with any member of the jury on anything concerning the case only in writing, or orally here in open court. If you send out a question, I will consult with the parties as promptly as possible before answering it, which may take some time. You may continue with your deliberations while waiting for the answer to any question. Remember that you are not to tell anyone, including me, how the jury stands, numerically or otherwise, until after you have reached a unanimous verdict or have been discharged.

First Circuit Pattern Criminal Jury Instruction 6.05.

CERTIFICATE OF SERVICE

I, Benjamin M. Greenblum, hereby certify that this document was electronically filed and served using the Court's ECF system on October 14, 2014.

/s/ Benjamin M. Greenblum
Benjamin M. Greenblum